

**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.)	
a Private Limited Company)	
of the United Kingdom)	
)	
Defendants.)	
)	

**DePuy Mitek's Memorandum in Opposition to Arthrex, Inc.'s and Pearsalls Ltd.'s Motion
in Limine To Preclude Dr. Brookstein From Testifying As an Expert at Trial Regarding
the Effect of Coating on FiberWire's Properties or Performance**

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I. Introduction

Arthrex, Inc.'s and Pearsalls Ltd.'s (collectively, "Arthrex") motion to preclude DePuy Mitek, Inc's ("Mitek") expert Dr. Brookstein from testifying presents the following issue:

Whether an award-winning, textile engineer with over thirty years of experience in studying, teaching about, designing, manufacturing and evaluating textile structures, including sutures, and their properties is qualified as an expert to testify about whether adding a material (*i.e.*, coating) to a textile structure (*i.e.*, a suture) has a material effect on the textile structure's properties?

Mitek's expert, Dr. Brookstein, has been designing, evaluating, testing, and teaching about textile structures and their properties, including sutures, for over thirty years. Dr. Brookstein has advanced degrees in textile engineering, has years of industry experience with sutures and other textile structures, and has taught numerous undergraduate and graduate courses in textiles. He currently serves as the Dean of the School of Engineering and Textiles at Philadelphia University. Dr. Brookstein's education and experience qualify him as an expert on the issue of the effects of adding a material (*i.e.*, a coating) to a textile structure (*i.e.*, FiberWire sutures).

II. Factual Background

A. Sutures Are Textile Structures

The field of textile engineering includes the study of fibers, yarns, and structures made from fibers and yarns (Ex. 1 at ¶3). It also includes a study of the properties of fibers, yarns, and structures made from fibers and yarns (*id.*). These properties include the basic mechanical and textile properties such as strength, friction, pliability, fiber-to-fiber interaction, and bending stiffness to name a few (*id.*).

Multifilament sutures, which are discussed in this case, are made by processing fibers to make yarns, and then braiding the yarns to make a suture (*id.* at ¶4). As sutures are made from fibers and yarns, suture are undisputedly textile structures and are widely recognized as textile

structures (*id.*). Notably, Arthrex does not dispute that a suture is a textile structure with textile properties.

Suture properties are textile engineering properties (*id.* at ¶5). Suture properties include strength and handleability (*id.*). Handleability, including features such as knot run-down and knot tie-down, is dependent upon basic textile properties such as friction, stiffness, pliability, fiber-to-fiber interaction and bending strength (*id.*).

B. The Question of Whether FiberWire’s Coating Has a Material Effect is a Question Regarding the Effect of a Material on a Textile Structure

The Court has defined the novel and basic characteristics of the invention claimed in U.S. Patent No. 5,314,446 as:

(1) a surgical suture; (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture

(Arthrex Ex. 1 at 18-19). Since a suture is a textile structure and the properties defined by the Court’s Order are textile properties (Ex. 1 at ¶¶3-6), the materiality question regarding FiberWire’s coating is whether adding a material (*i.e.*, coating) to a textile structure (*i.e.*, a suture) has a material effect on a textile structure’s properties as defined in the Court’s Order. The answer to this question is a textile engineering question that involves the principles, theory, and expertise of a textile engineer.

III. Law Regarding Qualifying an Expert

Under Fed. R. Evid. 702 a witness may be qualified as an expert “by knowledge, skill, experience, training, or education.” There is no mechanical formula for determining whether an expert is qualified to offer opinion evidence in a particular field. *Santos v. Posadas De Puerto Rico Associates, Inc.*, 452 F.3d 59, 63 (1st Cir. 2006). “The test is whether, under the totality of

the circumstances, the witness can be said to be qualified as expert in a particular field, through any one or more of the five bases enumerated in Rule 702-knowledge, skill, experience, training, or education.” *Id.* at 64 (citing *United States v. Shay*, 57 F.3d 126, 132 (1st Cir. 1995); *United States v. Paiva*, 892 F.2d 148, 160 (1st Cir. 1989)). A witness need not be a specialist to qualify as an expert. *Bado-Santana v. Ford Motor Co.*, 482 F. Supp. 2d 192, 196 (D. P.R. 1997).

This Court decides the admissibility of expert opinions under Fed. R. Evid. 104(a).

IV. Dr. Brookstein Is Qualified To Discuss Whether FiberWire’s Coating Has a Material Effect on the Novel and Basic Characteristics of the Invention

Arthrex raises three main arguments for excluding Dr. Brookstein’s testimony. First, Arthrex argues that Dr. Brookstein lacks the requisite qualifications for opining regarding the effects of FiberWire’s coating. Second, Arthrex argues that Dr. Brookstein should be disqualified because he did not agree to Arthrex’s attorney’s assertion regarding the effects of all coatings. Third, Arthrex argues that Dr. Brookstein should be disqualified because he could not recall at his deposition reviewing three documents from the mountains of information that he considered in this case. Arthrex’s objections are without merit, particularly for the extraordinary relief that it requests, the exclusion of expert testimony. Mitek addresses each of Arthrex’s arguments below.

A. Arthrex’s Argument That Dr. Brookstein Lacks the Requisite Qualifications Is Erroneous

Arthrex’s argument that Dr. Brookstein lacks the requisite qualifications is meritless for three reasons. First, as required by Fed. R. Evid. 702, Dr. Brookstein has the expert qualifications by virtue of his knowledge, skill, training, and technical experience. Second, Arthrex’s argument, basically that Dr. Brookstein lacks sufficient specialization in coatings, is legally erroneous. Third, by Arthrex’s own admission, Dr. Brookstein is a person of ordinary

skill in the art and has the requisite qualifications to opine on the issue of materiality to one of ordinary skill in the art.

1. Dr. Brookstein Has The Technical Knowledge, Skill, Training and Experience to Opine on the Effect of FiberWire's Coating

Dr. Brookstein has been studying, designing, evaluating, and testing textile structures for over thirty years¹ (Ex. 1 at ¶1). It is well known that sutures are textile structures and suture properties are textile engineering properties (*id.* at ¶¶3, 5, citing references), and Arthrex submits no evidence to the contrary. Because a suture is a textile structure and therefore has textile properties, the relevant question is whether adding a material (*i.e.*, FiberWire's coating) to a textile structure (*i.e.*, the FiberWire suture) has a material effect on the physical properties of the constituent elements of textile structure. For this issue, Dr. Brookstein is qualified under Rule 702 because he has spent his entire career studying textile structures and their properties (*id.* at ¶6). Lest there be any doubt, Mitek discusses his qualifications by virtue of his education, academic experience, and industry experience.

a) Dr. Brookstein is Qualified By Virtue of His Education

Dr. Brookstein is qualified to discuss the effect of adding a material (*i.e.*, a coating) to a braided textile structure (*i.e.*, a suture) because he studied texture structures and the relevant properties while obtaining his Bachelor of Textile Engineering from the Georgia Institute of Technology, commonly known as Georgia Tech, in 1971, a Masters in Science in Textile Technology from the Massachusetts Institute of Technology (MIT) in 1973, and a doctorate in the field of mechanical engineering from MIT in 1976 (*id.* at ¶7). While studying for all three degrees, Dr. Brookstein studied the design, manufacture, evaluation, and testing of an extensive range of textile structures (*id.*). This includes evaluating textile structures, including fibers,

¹ Neither Dr. Brookstein, Mitek's non-infringement expert, nor Dr. Mukherjee, Arthrex's non-infringement expert, is a surgeon.

yarns, and braided structures, for properties such as strength, stiffness, pliability, friction, torsional properties, compression, thermal properties, and electrical properties (*id.*) This also included the study and effects of surface treatments, including coatings, on fibers, yarns, and fabrics (*id.*). At Georgia Tech, Dr. Brookstein studied fiber science, and among the topics he studied in this course were suture fiber properties (*id.* at ¶8). Further, at Georgia Tech and MIT, he studied the design, manufacture, evaluation, and testing of textile structures including properties such as tensile strength, bending stiffness, pliability, surface friction, and fiber-to-fiber interaction (*id.*). While at MIT and Georgia Tech, Dr. Brookstein also studied manufacture of textile structures and the effects of manufacturing methods on textiles, including processes such as extruding, braiding, coating, twisting, texturing, heating, and stretching (*id.*).

As a graduate student at MIT, Dr. Brookstein worked part-time at Albany International Research Co. on a project involving coating fabrics (*id.*). This involved a coating process that included running a woven structure through a dip bath and a heated oven to cure the coating (*id.*). Also, at MIT, Dr. Brookstein studied the frictional properties associated with a thin coating (known as spin finish) that was placed on textile yarns to facilitate the draw texturing process, frictional properties between the fibers themselves, and other mechanical elements, and “spin finishing” which is a polymeric coating applied to yarns prior to final heating and stretching (*id.* at ¶9). Thus, as Dr. Brookstein has extensively studied the effect of materials, including coatings, on textile properties, the same properties that are at issue here, namely strength and frictional properties, he is qualified as an expert.

b) Dr. Brookstein is Qualified by Virtue of His Academic Career

Dr. Brookstein is also qualified as an expert by virtue of his academic career. As a professor from 1975 to 1980 in the School of Textile Engineering at Georgia Tech, Dr.

Brookstein taught a course entitled Fiber Science which covered many aspects of fiber manufacturing, development, and application, including but not limited to extruding fibers for a wide-range of applications including sutures (*id.* at ¶10). Dr. Brookstein also taught about the effects of fiber friction on textile structural properties, the control of fiber friction using spin finishes and other coatings, tensile properties of fibers including time effects associated with viscoelastic behavior, bending properties of fibers, yarns and cords, torsional properties for fibers, yarns and cords, and transverse compressional properties of fibers, yarns and cords (*id.*). Based on his doctoral studies at MIT, Dr. Brookstein also taught about the effects of heating and stretching on polymeric fibers and yarns on their mechanical properties (*id.*).

As the Dean of the School of Engineering and Textiles at Philadelphia University, Dr. Brookstein taught a graduate course entitled “Technological Development in Textiles” that also dealt with fiber manufacturing including extruding fibers for many applications, including biomedical devices and sutures (*id.* at ¶11). At Philadelphia University, Dr. Brookstein also taught a course in engineering statics and developed a course in mechanics of materials for mechanical engineers (*id.*). In these courses, he taught the principles and theory of bending, stiffness, pliability, and strength (*id.*). He taught similar concepts while serving as an adjunct professor at Northeastern University (*id.*). Thus, Dr. Brookstein is qualified by virtue of his academic career.

c) Dr. Brookstein is Qualified by Virtue of His Industry Experience

Dr. Brookstein is also qualified by virtue of his industry experience with sutures. In the industry, Dr. Brookstein spent three years managing a project for U.S. Surgical, a major suture company, that included designing, evaluating, manufacturing, and testing new braided multifilament sutures (*id.* at ¶¶12-15). In doing so, he evaluated, designed and manufactured

sutures for surface friction properties, surface roughness, knot strength, pliability/stiffness, and tensile strength (*id.* at ¶15).

In addition to developing the sutures in conjunction with U.S. Surgical, Dr. Brookstein supervised the manufacturing of the prototype sutures (*id.* at ¶14). Dr. Brookstein made fibers by extruding the fibers from the polymers, made yarns with the extruded fibers, and braided the yarns to make sutures (*id.*). In addition to designing and manufacturing sutures for U.S. Surgical, Dr. Brookstein evaluated the sutures that were made for surface friction properties, surface roughness, knot strength, pliability/stiffness, tensile strength and stiffness (*id.* at ¶15). Although he could not recall at his deposition whether the sutures were coated, because the project was about twenty years ago, Dr. Brookstein refreshed his my memory by contacting Dr. Hermes, his principal contact at U.S. Surgical, and was reminded that U.S. Surgical did coat the sutures (*id.*). Although U.S. Surgical did the actual coating of the sutures, Dr. Brookstein worked with them to assess the sutures and their performance (*id.* at ¶14). This was an iterative process through the project (*id.* at ¶15). For example, Dr. Brookstein worked with U.S. Surgical to design, manufacture, and evaluate, one suture construct, and then design, manufacture, and evaluate another suture construct (*id.*). Thus, Dr. Brookstein has considerable experience in designing, manufacturing, and evaluating braided multifilament sutures. Contrary to Arthrex's assertion without citation, there is no evidence that Dr. Brookstein's role in this project was "limited to braiding" (Arthrex Br. at 2, asserting without citation).

Dr. Brookstein has extensive experience in coating and the effects of coating on numerous textile structures. He has been involved in the design of coated braided textile products, including the selection of suture materials, the braid construction, and the selection of the coatings (Ex. 1 at ¶16). The factors that he considered in designing the products included at

least surface friction properties, pliability/stiffness, tensile strength, and stiffness (*id.*). For example, Dr. Brookstein has: (i) evaluated the coating of textile yarns that were ultimately manufactured into tire cords; (ii) consulted with the Union Carbide Corporation regarding coated carbon fibers and yarns and developed surface treatments for the fibers and yarns; (iii) consulted with the Tennessee Eastman Division of Eastman Kodak, regarding PET yarns having spin finishes and coatings and evaluated their frictional properties; (iv) developed a unique coating process for a braided sucker rod; (v) worked with braided yarns and fibers to develop a composite truss tube for the US Army Fort Belvoir Corps of Engineers Laboratory; (vi) developed a braided rocket motor igniter for a ballistic missile having an igniter fabricated from polymeric coated textile yarns; and (vii) developed a braided air beam in which a surface coating was applied to the braided structure (*id.* at ¶¶16-24). Thus, Dr. Brookstein has worked with many types of braided structures, many of which were either impregnated with coating, surface coated, or used yarns having a surface coating (*id.* at ¶24). He has designed, manufactured, and tested these textile structures for the mechanical properties that Arthrex contends are relevant to this case such as tensile strength, pliability, bending stiffness, and frictional properties (*id.*). He has studied first hand the difference in effects of surface coatings and coatings that impregnate braided structures (*id.*).

Dr. Brookstein also worked on other medical devices including resorbable bone plates, resorbable bone screws for Acufex, which is now part of Smith & Nephew (Ex. 2 at 45:19-24). In addition, he has designed, manufactured, and tested vascular grafts for many properties including bending strength and stiffness, tensile strength, fluid pressure containment, and surface properties (Ex. 1 at ¶23).

Not only has Dr. Brookstein studied, taught, and worked with braided textile structures for virtually his entire career, he has received numerous accolades for his work in evaluating these structures. For example, he received the prestigious Techtextil Innovation Prize in 1994, and the American Society of Testing and Materials (ASTM) Harold DeWitt Smith Award for outstanding achievement in the field of textile fiber utilization (*id.* at ¶27). He has also been recognized as an expert by his peers through his election to various high-level positions in industry organizations (*id.*).

d) Dr. Brookstein is Qualified Under Fed. R. Evid. 702

In summary, Dr. Brookstein is qualified as an expert to assess whether adding a material (*i.e.*, a coating) to a textile structure (*i.e.*, a suture) has a material affect on the novel and basic characteristics of the invention because he has studied, taught, and worked on textile structures, including the effects of coatings for his entire career. Under Fed. R. Evid. 702, Dr. Brookstein need only be qualified by virtue of knowledge, skill, experience, training, or education. But Dr. Brookstein is qualified by virtue of all of them.

In its motion, Arthrex basically ignores Dr. Brookstein's entire career and instead focuses on deposition sound bites. For example, Dr. Brookstein testified to some of his background expertise throughout his deposition, but Arthrex ignores that testimony in its motion (Ex. 2 at 59:11-61:18; 71:1-21; 72:13-25; 81:16-84:6; 88:11-20; 89:9-90:23; 94:13-95:14; 223:25-226:20). In fact, Dr. Brookstein testified that his experience regularly involved evaluating textile coatings:

I indicated it was almost a regular practice of mine because I was very involved in applying coatings to textile structures and seeing to what extent the coating had an effect on the structure.

(*id.* at 226:7-11). But Arthrex cannot disqualify Dr. Brookstein by ignoring the relevant evidence.

2. Arthrex's Argument That Dr. Brookstein Is Not Qualified Because He Is Not a Coating Specialist Should Be Rejected As Legally Erroneous

Arthrex characterizes Dr. Brookstein's experience with sutures as limited and therefore argues he is not qualified as an expert to testify about the effect a coating has on Arthrex's FiberWire suture. But Arthrex's standard for the qualifications of an expert is unduly restrictive and erroneous. "[A]n expert witness is not strictly confined to his area of practice, but may testify concerning related applications; a lack of specialization does not affect the admissibility of the opinion, but only its weight." *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991); *See Libbey v. Wabash Nat'l Corp.*, 2002 U.S. Dist. LEXIS 19039, at *10-*11 (D. Me. Oct. 7, 2002) (Ex. 3).

This principle was reiterated in the *Watson* case, a case cited by Arthrex itself (Arthrex Br. at 3, 7). In *Watson*, the Court ruled that the expert was qualified to discuss a particular device (an electromechanical saw) because he was an expert in electromechanical devices in general:

I find that Wilder's education, training, and practical experience working as a professional engineer, and in his designing, manufacturing and marketing *electromechanical devices* are sufficient permit his expert testimony for such assistance as the jury to credit in understanding the technical and scientific evidence regarding *the saw – an electromechanical device*.

Watson v. Electrolux Prof'l Outdoor Prods, 2006 U.S. Dist. LEXIS 54386, *4 (D. Mass. Aug. 4, 2006)(emphasis added) (Arthrex Ex. 4). The case law is replete with decisions permitting experts to testify on a subject matter even if they had not specialized in that specific area.²

² See also *Bassett Furniture Indus. of North. Carolina, Inc. v. NVF Co.*, 576 F.2d 1084, 1090-91 (5th Cir. 1978) (expert allowed to testify regarding sanding procedures used in furniture manufacturing although he was not familiar with furniture industry); *Santos*, 452 F.3d at 63-64 (affirming admission of expert testimony concerning slip on pool steps where expert had extensive experience with slip-and-fall accidents but no experience with pools); *Gaydar v.*

The *Libbey* case is also instructive. In *Libbey*, the defendant's motion to exclude expert testimony was denied. *Libbey*, 2002 U.S. Dist. LEXIS 19039, at *13. There, the expert was to testify that "the painted metal surfaces of the I-beam flanges in the trailer bed would have been slippery when wet, that wetness of the trailer bed would have been a normally expected condition of operation of the truck and that the presence of these surfaces contributed significantly to the plaintiff's injuries." *Id.* at *8. The Court stated that even though the expert admitted that he lacked "familiarity with the use, design and manufacture of flatbed trailers," that did not automatically disqualify him from expressing an expert opinion about the slip resistance of a portion of the surface of the defendant's flatbed trailer design. *Id.* at *10. The Court ruled that the expert's background in slip resistance of metal surfaces is sufficient to qualify him to testify on the issue. *Id.* at *11. Similarly, here, sutures are a type of textile structure, and Arthrex agrees that Dr. Brookstein is an expert in textile structures (Ex. 1 at ¶¶2-5; Arthrex Br. at 8). Therefore, Dr. Brookstein is qualified to discuss the effects of a coating on a textile structure, including a suture. Whether he has a specialty in coatings is simply irrelevant to admissibility.

3. Dr. Brookstein Is Qualified to Discuss FiberWire's Coatings' Effects on FiberWire's Performance and Properties Because He is Undisputedly a Person of Ordinary Skill in the Art

Arthrex admits that the legal standard for determining whether FiberWire's coating has a material effect on the novel and basic properties of the invention is whether the "effect is of

Sociedad Instituto Gineco-Quirurgico y Planificacion Familiar, 345 F.3d 15, 19-20 (1st Cir. 2003) (admitting expert testimony of general practitioner, who had performed only two pelvic examinations since his internship, and was not a specialist in gynecology or obstetrics on malpractice issue in the area of gynecology or obstetrics); *Colegrove v. Cameron Mach. Co.*, 172 F. Supp. 2d 611, 635-36 (W.D. Pa. 2001) (permitting expert in mechanical engineering to testify that condition of mechanism was defective even though he had no experience in designing mechanism at issue or with machine on which mechanism operated); *Bado-Santana*, 482 F. Supp. 2d at 196 (admitting testimony based on education, experience and training and rejecting argument that because expert did not have specific expertise in an area that she could not testify as an expert).

importance or of consequence to those of ordinary skill in the art” (Ex. 4 at 4; *quoting PPG Indus., Inc. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998)). Arthrex and its expert, Dr. Mukherjee, allege that the person of ordinary skill in the art is a person having “an undergraduate degree in engineering or science and several years (*e.g.*, approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications” (Ex. 5 at 10).³ At his deposition, Arthrex’s Dr. Mukherjee further explained that a person of ordinary skill in the art includes a person with a science degree and experience in extruding fibers for use in sutures:

- Q. Okay. Is a person who has engineering science degree and his only experience is in extruding fibers for use in sutures a person of ordinary skill in the art?
- A. The answer is yes.

(Ex. 7 at 541:7-11).

Dr. Brookstein clearly satisfies Arthrex’s definition. Dr. Brookstein not only has an undergraduate degree in engineering or science (*e.g.*, a Bachelor of Textile Engineering from Georgia Tech), but he also has a Doctor of Science in the field of Mechanical Engineering from the Massachusetts Institute of Technology (Ex. 1 at ¶¶7, 9). Further, Dr. Brookstein has approximately three years of experience in manufacturing and/or processing of fibers and sutures which can be used for biomedical applications (*id.* at ¶¶12-13). Dr. Brookstein worked on the design, development, and manufacturing of sutures for at least three years while at Albany International Research Company (*id.* at ¶¶13-15). While conducting this work, Dr. Brookstein processed fibers and manufactured sutures (*id.*). These facts are undisputed. Thus, Dr.

³ Another of Mitek’s experts, Dr. Hermes, who opined mainly on validity issues, provided a definition of the person of ordinary skill in the art that differed from Arthrex’s definition (Ex. 6 at ¶¶30, 31). Dr. Brookstein is a person of ordinary skill in the art under Dr. Hermes’ definition as well (Ex. 1 at ¶¶1-24).

Brookstein undisputedly qualifies as a person of ordinary skill in the art, and is qualified to discuss the effects of FiberWire's coating on the novel and basic characteristics of the invention.

B. Dr. Brookstein's Refusal to Agree with Arthrex's Attorney Assertion is Not a Basis For Disqualifying Him As An Expert

Arthrex argues that Dr. Brookstein is not qualified as an expert in the relevant area because he would not agree to Arthrex's inadmissible attorney assertion that all multifilament suture coatings supposedly necessarily improve tactile smoothness, knot tie-down, and pliability (Arthrex Br. at 3-4). But contrary to Arthrex's assertions, Dr. Brookstein's refusal to agree to such broad generalizations shows that he is in fact an expert.

Dr. Brookstein need not agree to Arthrex's attorney assertion because the evidence is to the contrary. The 446 Patent itself explains that some particular coatings can have a negative impact on suture handleability because they may substantially interfere with fiber-to-fiber movement:

Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability.

(Ex. 8 at 1:18-22). Further, the 446 Patent describes a specific example of a coating that is applied by "solution casting, melt coating, or extrusion coating" and explains that this suture also had similar handleability deficiencies (*id.* at 2:10).

Also, as the 446 Patent explains with its examples in the background of the invention section, there are many different types of coatings that can be applied in many different ways (*id.* at 1:26-2:13). Dr. Brookstein was not asked for purposes of this case to opine on whether every suture coating material applied in every possible way necessarily has certain effects on multifilament sutures. The relevant issue in this case has to do with FiberWire's coating, not all coatings, and whether FiberWire's coating has a material effect. If Arthrex wants to try to prove

its broad, general statements at trial and try to somehow tie them to the FiberWire sutures and the issue of materiality, it is certainly free to do so, but there is no requirement that Dr. Brookstein agree with Arthrex's counsel's view of sutures in order to qualify as an expert.

C. Dr. Brookstein Is Not Disqualified From Testifying Merely Because He Could Not Recall Certain Documents At His Deposition

Amazingly, Arthrex makes the absurd argument that, merely because Dr. Brookstein could not recall at his deposition reviewing three documents, none of which discusses FiberWire or its coating, and which were among the reams of information considered, that he is somehow disqualified as an expert. Notably, Arthrex cites no case with such a holding.

Arthrex's criticisms are unjustified for three reasons. First, Arthrex's attorney spin that Dr. Brookstein supposedly did not review certain documents is wrong. Second, Dr. Brookstein reviewed a mountain of evidence regarding FiberWire and its coating, and the documents, which he could not remember, do not discuss FiberWire or its coating (Arthrex Exs. 6-8). Further, they have marginal, if any, relevance to the issues in this case. Third, a failure to remember or even review a few documents is no basis for disqualifying an expert who has reviewed a plethora of evidence. Mitek discusses each of these reasons below.

Arthrex alleges that Dr. Brookstein did not review three documents, Arthrex's Exs. 6-8. But Arthrex is just wrong. These documents were exhibits to Dr. Mukherjee's, Arthrex's expert's, Rebuttal Report (Ex. 9). Arthrex ignores the fact that, in the very deposition testimony to which it cites, Dr. Brookstein stated that he had reviewed the documents because they were exhibits to Dr. Mukherjee's report:

Q. Did you review the exhibits to Dr. Mukherjee's reports?

A. Yes.

(Arthrex Ex. 5 at 170:11-13). Arthrex's attempted spin on Dr. Brookstein's testimony cannot change the clear fact that he had reviewed the exhibits. Thus, Arthrex's assertion is just wrong, and no basis for disqualifying Dr. Brookstein.

Further, contrary to Arthrex's attorney spin, when confronted with the specific documents, Dr. Brookstein did not state that "he had never seen" the three documents (Arthrex's Br. at 5). Rather, in the portions of Dr. Brookstein's testimony to which Arthrex cite, Dr. Brookstein merely stated "I don't recall seeing this" and "I do not recall seeing this document before" for two of the documents (Arthrex's Ex. 5 at 177:14-178:5; 182:11-183:1), and with respect to the other document, Dr. Brookstein testified that he had reviewed the exhibits to Dr. Mukherjee's reports (Arthrex's Ex. at 170:11-13). Thus, Dr. Brookstein did not state that he had unequivocally not reviewed the documents.

Although Dr. Brookstein did not recall the three documents at his deposition, he can hardly be criticized for not remembering them because a deposition is not a memory test. Dr. Brookstein submitted four expert reports in this case that total about 100 pages in length (Exs. 10-13). In doing so, he reviewed about 150 documents, many of which are voluminous (Exs. 14-17). Further, he reviewed three expert reports from Arthrex's experts, two expert reports from Dr. Mukherjee and one from Dr. Gitis. Also, he reviewed reams of test data⁴ that Dr. Gitis generated (Exs. 16-17). Dr. Brookstein can hardly be criticized for not remembering three patents among the plethora of information he reviewed.

Notably, Arthrex's counsel chose to place the three patents in front of Dr. Brookstein without providing any context for the documents (Arthrex's Ex. 5 at 170:2-13; 174:17-21; 182:11-16). Arthrex's counsel could have shown Dr. Brookstein Dr. Mukherjee's expert report

⁴ Dr. Gitis's test data fills several boxes with each page being a spreadsheet of data. Mitek has not submitted the data here, but can do so on request.

and how the three documents were cited by Dr. Mukherjee to place the patents in context. But he chose not to. Rather, he made the deposition a memory test. Dr. Brookstein should not be disqualifying for failing to recall three documents, without any context, when he had reviewed boxes of documents in rendering his opinions.

Finally, whether or not Dr. Brookstein reviewed three documents having marginal, if any, relevance is no basis for disqualifying him. The three documents that Arthrex makes such a big deal about do not even mention FiberWire or its coating (Ex. 9 at Exs. 6-8). Rather than focusing on coatings on other suture products, Dr. Brookstein focused on the 446 Patent, FiberWire, and FiberWire's coating.

As explained above, Dr. Brookstein reviewed a wealth of information related to FiberWire (Exs. 14-17). Dr. Brookstein considered the 446 Patent's teachings about what is material to the invention (Ex. 14). Dr. Brookstein traveled to rural England and witnessed first-hand Pearsalls' manufacturing processes including its coating process (Ex. 10 at ¶27). He inspected FiberWire (Ex. 13 at ¶¶38-40). He reviewed Pearsalls' documents regarding its manufacturing processes, including those related to coating (Ex. 10 at ¶40). He reviewed test data related to FiberWire (Exs. 10 at ¶¶40-42). He visually inspected and weighed FiberWire to determine the amount of coating (Ex. 10 at ¶¶27; Ex. 13 at ¶¶38-40). He considered how FiberWire was developed and the developer's description of the importance of the heterogeneous braid to the invention (Ex. 10 at ¶¶24-26). He also considered Dr. Burks' testimony regarding FiberWire and its coating (Ex. 12 at ¶¶50-51).⁵ Thus, the mere fact that Dr. Brookstein could not

⁵ Arthrex improperly tries to criticize Dr. Brookstein for not considering attorney-work product, privileged information regarding tests that Ethicon performed with samples that Arthrex has provided to Mitek before the suit was filed (Arthrex Br. at 6-7). This criticism is improper because Arthrex cannot ask for an adverse inference based on a claim of work product or privilege. See *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d

recall three documents, that do not discuss either FiberWire or its coating, is no basis for excluding him when his opinions are based on the pertinent information regarding FiberWire itself.⁶

V. Arthrex's Motion Does Not Apply To Many of Dr. Brookstein's Other Opinions And Therefore Arthrex Waived Its Right To Object to His Opinions On Those Issues

A. Arthrex Did Not Move With Respect to Dr. Brookstein's Opinions Regarding the Reverse Doctrine of Equivalents, Tipping, Contributory Infringement, and Other Issues

Arthrex has asserted that there is no infringement under the reverse doctrine of equivalents and because the very ends of its FiberWire suture are tipped. Further, Pearsalls has asserted that it does not contributorily infringe under 35 U.S.C. §271(c). Dr. Brookstein set forth his opinions regarding these issues in his expert reports. For example, one section of his Rebuttal Expert Report is entitled "Reverse Doctrine of Equivalents" (Ex. 10 at ¶63), a section of his first expert report is entitled "Opinions Regarding Contributory Infringement" (Ex. 13 at ¶¶67-72), and he has several paragraphs discussing his opinions regarding the tipped ends of Arthrex's sutures (*id.* at ¶¶41-43). In footnote 1 of its brief, Arthrex asserts that its motion does not seek to exclude Dr. Brookstein from testifying about these subjects (Arthrex Br. at 1, n.1). Therefore, Dr. Brookstein should be permitted to opine regarding these issues.

1337, 1344 (Fed Cir. 2004). Significantly, the samples that were tested were apples and oranges because they had many differences in addition to coating, one was dyed, coated, stretched, and heated, and one was not. Mitek has submitted a motion *in limine* seeking to preclude Arthrex from making these improper arguments (D.I. 127 and 128).

⁶ Although Dr. Brookstein stated that he did not recall looking at other patents, he certainly did as he reviewed the prosecution history and a plethora of other documents related to FiberWire (Exs. 14-17).

B. Arthrex Did Not Move With Respect to Many of Dr. Brookstein's Opinions Regarding the Issue of Whether FiberWire's Coating Has a Material Affect on the Novel and Basic Characteristics of the Invention

Dr. Brookstein's opinions that FiberWire's coating does not have a material affect on the novel and basic characteristics of the invention are based on several issues for which Arthrex's motion is inapplicable. Arthrex's motion sought an "Order precluding Dr. Brookstein from testifying as an expert at trial regarding the effects of coating on FiberWire's properties or performance." One reason why Dr. Brookstein explains that FiberWire's coatings effects are immaterial to the novel and basic characteristics is that FiberWire's coating is precisely the type of coating that is described as immaterial in the patent. Arthrex did not address this issue in its motion, and therefore Dr. Brookstein should be able to discuss it.

VI. Conclusion

For the foregoing reasons, Arthrex's motion should be denied.

Dated: July 24, 2007

DEPUY MITEK, INC.,
By its attorneys,

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CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

**DePuy Mitek's Memorandum in Opposition to Arthrex, Inc.'s and Pearsalls Ltd.'s Motion
in Limine To Preclude Dr. Brookstein From Testifying As an Expert at Trial Regarding
the Effect of Coating on FiberWire's Properties or Performance**

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date *via* the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

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Dated: July 24, 2007

/s/ Erich M. Falke
Erich M. Falke

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Declaration of Dr. David Brookstein

I. Introduction

1. I am an expert, by virtue of my education and experience in studying, designing, evaluating, and testing textile structures, including sutures. I have studied textile structures and their properties for over thirty years. My curriculum vitae which discusses my career in the field of textiles is attached (Ex. 1). Starting from my undergraduate education in textile engineering at both Philadelphia College of Textiles and Science (now Philadelphia University) and Georgia Institute of Technology, commonly known as Georgia Tech, through my masters and doctoral studies in the field of textile engineering at the Massachusetts Institute of Technology (MIT), followed by five year as a professor of engineering at Georgia Tech, fourteen years of textile engineering research and development at Albany International Research Co., and my recent thirteen year experience as Dean of the School of Engineering and Textiles at Philadelphia University, I have spent over thirty years studying textile structures and their properties.

2. Among the issues I was asked to opine on is the question of whether FiberWire's coating has a material effect on the novel and basic characteristics of the invention claimed in U.S. Patent No. 5,314,446. The Court has defined the novel and basic characteristics of the invention as:

(1) a surgical suture; (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture."

Since a suture is a textile structure, the question that I am opining on is whether adding a material (*i.e.*, coating) to a textile structure (*i.e.*, a suture) has a material effect on a textile structure's properties as defined in the Court's Order. I am qualified to opine on this issue because I have studied, researched, designed, and evaluated the affects of changing materials and manufacturing processes on textile structures for my entire career, as discussed below.

II. Sutures are Textile Structures and Suture Properties are Textile Properties

3. The field of textile engineering includes the study of fibers, yarns, and structures made from fibers and yarns. It also includes a study of the properties of fibers, yarns, and structures made from fibers and yarns. These properties include the basic mechanical and textile properties such as strength, friction, pliability, fiber-to-fiber interaction, and bending stiffness to name a few.

4. Sutures are textile structures. Multifilament sutures, which are discussed in this case, are made by processing fibers to make yarns, and then braiding the yarns to make a suture. As sutures are made from fibers and yarns, they are textile structures and are widely recognized as textile structures. For example, the common reference books

HANDBOOK OF TECHNICAL TEXTILES (A. R. Horrocks et al. ed. 2000) (Ex. 2 at section 15.5 Implantable Materials) and TATSUYA HONGO ET AL. NEW FIBERS (2nd ed. 1997) (Ex. 3 at section 6.2 Biotechnology and Fibers) recognize sutures as textile structures. Textile sutures are regularly covered in the quarterly journal “Medical Textiles” published by Elsevier, a journal which I regularly review upon publication.

5. Suture properties are textile engineering properties. Suture properties include strength and handleability. Handleability, including features such as knot run down and knot tie down, is dependent upon basic textile properties such as friction, stiffness, pliability, fiber-to-fiber interaction and bending strength. Thus, handleability and strength are basic textile and mechanical properties that I have studied throughout my entire career.

6. Since a suture is a textile structure and the properties that are relevant in this case are textile properties, the question that I am opining on is whether adding a material (*i.e.*, coating) to a textile structure (*i.e.*, a suture) has a material effect on the textile structure properties. I am qualified to opine on this issue because I have studied, researched, designed, and evaluated the affects of changing materials and manufacturing processes on textile structures for my entire career. Below, I discuss some of my experience in the field of textile engineering during my over thirty-year career which qualifies me to discuss these subjects.

III. Education

7. My education includes a Bachelor of Textile Engineering from the Georgia Institute of Technology, commonly known as Georgia Tech, in 1971, a Masters in

Science in Textile Technology from the Massachusetts Institute of Technology (MIT) in 1973, and a doctorate in the field of mechanical engineering from MIT in 1976.

While studying for all three degrees, I studied the design, manufacture, evaluation, and testing of an extensive range of textile structures. This includes evaluating textile structures, including fibers, yarns, and braided structures, for properties such as strength, stiffness, pliability, friction, torsional properties, compression, thermal properties, and electrical properties. This also included the study and effects of surface treatments on fibers, yarns, and fabrics, including coatings.

8. At Georgia Tech, I studied fiber science, and among the topics I studied in this course were suture fiber properties. Further, at Georgia Tech and MIT, I studied the design, manufacture, evaluation, and testing of textile structures including properties such as tensile strength, bending stiffness, pliability, surface friction, and fiber-to-fiber interaction. While at MIT and Georgia Tech, I also studied manufacturing of textile structures and their effects on textiles, including processes such as extruding, braiding, coating, twisting, texturing, heating, and stretching. As a graduate student at MIT, I worked part-time at Albany International Research Co. on a project involving coating fabrics. This involved a coating process that included running a woven structure through a dip bath and a heated oven to cure the coating.

9. At MIT, my doctoral research was in the area of the dynamics of draw texturing. Also, during my doctoral studies at MIT, I frequently studied the frictional properties associated with a thin coating (known as spin finish) that was put on textile yarns to facilitate the draw texturing process. Draw textured yarns have been used in sutures. Draw texturing is a textile manufacturing process that involves twisting, heating and

stretching of polymeric fibers, such as PET. During my doctoral studies, I considered issues such as the frictional properties between the fibers themselves and other mechanical elements. Further, I studied the issue of “spin finish,” which is a polymeric coating applied to yarns prior to final heating and stretching.

IV. Academic Career

10. I taught as a professor from 1975 to 1980 in the School of Textile Engineering at Georgia Tech. I regularly taught a course entitled Fiber Science which covered many aspects of fiber manufacturing, development, and application, including but not limited to extruding fibers for a wide-range of applications including sutures. Other areas that I taught included determination and effects of fiber friction on textile structural properties, the control of fiber friction using spin finishes and other coatings, tensile properties of fibers including time effects associated with viscoelastic behavior, bending properties of fibers, yarns and cords, torsional properties for fibers, yarns and cords, transverse compressional properties of fibers, yarns and cords. Based on my doctoral studies at MIT, I also taught about the effects of heating and stretching on polymeric fibers and yarns on their mechanical properties.

11. I am the Dean of the School of Engineering and Textiles at Philadelphia University. As Dean and Professor in the School of Engineering and Textiles at Philadelphia University, I taught a graduate course entitled Technological Development in Textiles that also dealt with fiber manufacturing including extruding fibers for many applications, including biomedical devices and sutures. At Philadelphia University, I also taught a course in engineering statics and have developed a course in mechanics of materials for mechanical engineers. In these courses, I teach the principles and theory of

bending, stiffness, pliability, and strength. I taught similar concepts while serving as an adjunct professor at Northeastern University, while I was employed at Albany International Research Co.

V. Industry Experience with Multifilament Sutures

12. I worked at Albany International Research Co. for fourteen years. Albany International Research Co. was a contract research and development company whose services included, among other things, designing, manufacturing, and testing products for other companies and the government. I was the associate director in charge of identifying projects, writing and submitting proposals to clients, and managing the projects that we obtained. Since Albany International Research Co. was relatively small, I was personally involved hands-on, day-to-day with the projects that we obtained. One project that I personally submitted a proposal for, was hired for, and managed was for U.S. Surgical Corporation, a medical device company.

13. I spent about three years managing a project for U.S. Surgical that included designing, evaluating, manufacturing, and testing new braided multifilament sutures. I was involved in the design of these sutures including the selection of suture materials and the suture construction. The factors that we considered in designing the sutures included at least surface friction properties, surface roughness, knot strength, pliability/stiffness, tensile strength and stiffness.

14. In addition to developing the sutures in conjunction with U.S. Surgical, I supervised the manufacturing of the prototype sutures. We started with a polymer. We made fibers by extruding the fibers from the polymers. We made yarns with the extruded fibers, and we braided the yarns to make sutures. Although we did not coat the sutures at

Albany International, the sutures were coated by U.S. Surgical after we made them. At my deposition, I did not recall whether the sutures were coated, but since then I refreshed my memory by contacting Dr. Hermes. Dr. Hermes was my principal contact at U.S. Surgical, and he reminded me that U.S. Surgical did coat the sutures.

15. In addition to designing and manufacturing sutures for U.S. Surgical, I evaluated the sutures that we made for surface friction properties, surface roughness, knot strength, pliability/stiffness, tensile strength and stiffness. We performed these evaluations, which was our typical general practice, when developing new textile products for clients. Our standard operating practice at Albany International was to work with our clients as partners in developing the products. Our process was a back-and-forth, give-and-take type process with U.S. Surgical. Although U.S. Surgical did the actual coating of the sutures that we made at Albany International, we worked with them to assess the sutures and their performance, and then redesign, reconfigure and make new braided sutures. This was an iterative process through the project. For example, we would design, manufacture, and evaluate, one suture construct, and then design, manufacture, and evaluate another suture construct. Thus, I have considerable experience in designing, manufacturing, and evaluating braided multifilament sutures.

VI. Industry Experience with Coated Textile Structures

16. Throughout most of my career, I have been involved with the design, manufacturing, evaluation, and testing of braided textile products, including those that have been coated. I have been involved in the design of coated braided textile products including the selection of suture materials, the braid construction, and the selection of the coatings. The factors that we considered in designing the products included at least

surface friction properties, pliability/stiffness, tensile strength and stiffness. For example, as early as 1970, I was an undergraduate textile engineer/summer intern at Monsanto in Decatur, Alabama. There I worked on a project to improve the coating of textile yarns that were ultimately manufactured into tire cords.

17. When I was an assistant professor at Georgia Tech, I was a regular consultant to the Union Carbide Corporation regarding coated carbon fibers and yarns. This included developing surface treatments, including coatings, for carbon fibers to make them more suitable for braiding, weaving, and other textile manufacturing processes. Carbon fibers are generally very brittle and stiff. During the course of this work, we considered various surface finishes (*i.e.*, coatings) to make them more pliable during the manufacturing process because these brittle materials had to be bent during the manufacturing process.

18. While an assistant professor at Georgia Tech, I consulted for the Tennessee Eastman Division of Eastman Kodak, which produced PET yarns for the texturing process. Among the work that I did, was studying the effect of spin finishes or coatings on PET yarns, and how they affect the friction-texturing process. Friction-texturing uses the frictional properties between yarns and a ceramic disk that develops torque, which imparts twist in textured yarns in the manufacturing process. We were optimizing the PET yarn friction properties to obtain the desired yarn twist.

19. At Albany International Research Co., my job responsibilities included the design, manufacture, and testing of braided structures, including those that were coated. For example, I am an inventor of braided sucker rods that were developed to allow more energy efficient petroleum extraction (U.S. Patent Nos. 4,602,892 and 4,497,866). Part of my invention was the development of a unique coating and impregnation process for

the braided rods. The purpose of the coating and the impregnation was to bond the fibers to each other to create a composite structure with enhanced strength properties. In developing this product and process, I evaluated the coatings effects on the strength, stiffness, and fatigue resistance.

20. For the US Army Fort Belvoir Corps of Engineers Laboratory, I developed a unique braided composite truss tube for a bridge support. While doing so, we braided yarns and coated them to make the truss tube. Therefore, during this project, I evaluated the mechanical properties of the truss tube, which includes the effects of the coating used in the construction. This includes such properties as strength and stiffness.

21. For the US Air Force, I developed a braided rocket motor igniter for a ballistic missile and the igniter was fabricated from polymeric coated textile yarns produced by Newport Composites. On occasion, I participated in the selection and development of yarn coating systems in conjunction with the scientists and engineers at Newport Composites. During this project, I evaluated the surface friction of the coated braided yarns to optimize the braiding process.

22. For the US Army Natick Soldier Center, I developed a braided air beam in which a surface coating was applied to the braided structure after it was braided. The purpose of the surface coating was to make the air beam impermeable to air.

23. Also, I was the research leader for a project funded by Meadox Medicals (now Boston Scientific) that used textile sutures in the development of braided vascular grafts. We used braided sutures to make vascular grafts. This work included the design, manufacturing, and testing of the vascular grafts. We evaluated the grafts for many

properties including bending strength and stiffness, tensile strength, fluid pressure containment, and surface properties.

24. These are a few of the projects that I can recall. During the course of my consulting and research, I have worked with many types of braided structures, many of which were either impregnated with coating, surface coated, or used yarns having a surface coating. I have designed, manufactured, and tested these textile structures for all of the mechanical properties that are relevant to this case such as tensile strength, pliability, bending stiffness, and frictional properties. I have studied first hand the difference in effects of surface coatings and coatings that impregnate braided structures.

VII. My Opinions

25. My opinions are based on the examination of a textile structure, FiberWire. In forming my opinions in this case, I have studied the design, construction and manufacturing of FiberWire. I have examined FiberWire under magnification and its manufacturing processes. I measured FiberWire's coating. I have evaluated whether FiberWire's coating was a surface coating or a coating that impregnated the structure. I studied U.S Patent No. 5,134,446 to determine what it teaches coatings are material to the claimed invention's characteristics. I studied the extent to which FiberWire's coating is applied to FiberWire. I studied FiberWire's design process. Some of the basis for my opinions includes the testing that Arthrex and Pearsalls have performed. For example, Arthrex tested two types of homogeneous sutures and found them to be unacceptable, and found a suture having the improved braid construction claimed in the 446 Patent to have improved properties. I also studied Pearsalls testing data of sutures that had been coated, heated, and stretched, against those that have not been coated, heated, and stretched.

This work included the evaluation of a textile structure and the evaluation of a textile structure's properties. This is precisely what I have been studying, teaching, and working on for my career.

26. I have also considered Arthrex's experts' opinions and the testing and analysis that they performed. For example, Dr. Norman Gitis submitted a test report on behalf of Arthrex discussing the testing of certain sutures for various textile properties. I analyzed his report, his testing as described in his report, and his test data. I recognized inconsistencies in his tests and data, which I described in one of my expert reports. I understand because of my work, Dr. Gitis reevaluated his work, and is now describing that his tests were performed differently than originally stated in his expert report.

VIII. Recognitions

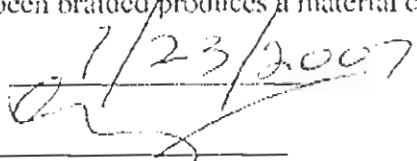
27. I have been recognized by my world-wide peers in the field of textile engineering and science by my award of the Techtextil Innovation Prize in 1994, my receiving the American Society of Testing and Materials (ASTM) Harold DeWitt Smith Award, an award for outstanding achievement in the field of textile fiber utilization. I have been elected to the grade of Fellow of the Textile Institute (UK) and Fellow of the American Society of Mechanical Engineers. I was elected President of The Fiber Society, an international professional society of fiber scientists and engineers. The Fiber Society is concerned with Advancement of scientific knowledge pertaining to fibers, fiber based products, and fibrous materials. I have served twice as the Chair of the Textile Engineering Division of the American Society of Mechanical Engineers. The Fiber Society has recognized me with the award for distinguished achievement in fiber science.

This award is presented to individuals under the age of 40 who have made significant contributions to the field. It is intended to recognize early achievement and to stimulate continuing commitment to the field of fiber science. As a member of The Fiber Society, I was twice appointed a Fiber Society Lecturer and visited many national colleges and universities to lecture on the use of advanced fiber materials for technical textile applications such as sutures.

IX. Summary

28. One of the issues I have been asked to opine is if a change in a material, such as adding a coating, materially affects a suture's properties. I believe that my substantial education, work, and experience the field of textile engineering (including fiber manufacturing, braiding and coating and testing and evaluation) and recognition by my international peers as leading textile scientist and engineer over a period of 35 years makes me qualified to opine of whether the coating applied to the FiberWire suture after it has been braided produces a material change to the braided suture structure.

Dated: 7/23/2007



Dr. David Brookstein

EXHIBIT 1

David Brookstein, Sc.D.
Dean and Professor of Engineering
Philadelphia University
Philadelphia, PA 19144
(215) 951-2751

Curriculum Vitae

Education:

- Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.
- Bachelor of Textile Engineering, Georgia Tech, 1971.
- Harvard University School of Business Summer Program on Research Management, 1990.
- Harvard University Graduate School of Education MLE Summer Program, 1998

Professional Experience:

Philadelphia University

1994 - Present Dean and Professor of Engineering
School of Textiles and Materials Technology (soon
to be the School of Engineering and Textiles)

Chief academic and financial officer for a school with undergraduate majors in industrial and systems engineering, textile engineering (ABET accredited), textile technology, textile design, fashion design and fashion industry management. Master of Science programs are offered in textile engineering, textile design, textile marketing, global textile marketing, on-line MBA in textile and apparel marketing and fashion-apparel studies. Developed first Philadelphia University program, - Ph.D. in textile engineering and science. Principal Investigator for largest outside funded research grant received by Philadelphia University, \$2.7 million DoD grant for the Laboratory for Engineered Human Protection. Philadelphia University Program Leader for the National Textile Research Center, a \$10 million/annum grant for a consortium of universities that include Auburn University, Georgia Tech, North Carolina State University, Clemson University, UMASS-Dartmouth, Cornell University and University of California-Davis. Led the development of the Philadelphia University Research Center in the Manayunk section of Philadelphia.

Harvard University

2002 – 2003 Visiting Scholar
Harvard University Center for Textile and Apparel
Research (Division of Engineering and Applied Sciences)

Albany International Research Co. - Mansfield, MA

1992 - 1994 Associate Director
1983 - 1992 Assistant Director
1980 - 1982 Senior Research Associate

Directed all activities of the professional engineering group responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. Accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous preforms for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures. Engineering innovations led to 11 US patents and many other inventions protected by trade secret. Member of the senior management staff of the organization.

Northeastern University - Boston, MA

1981-1983 Adjunct Professor in Mechanical Engineering

Taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

Georgia Institute of Technology, College of Engineering

1975 - 1980 Assistant Professor of Textile Engineering

Taught and conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems. Obtained substantial funding from US DOE and US DOD. Active participant in College of Engineering co-op undergraduate programs.

Outside Professional Activities:

- Advisory Board of the College of Engineering, Georgia Tech.
- Member of the University City Science Center Research Provost Roundtable
- Adjunct Full Professor, North Carolina State University
- President, The Fiber Society (1996)
- Chairman, Textile Engineering Division-American Society of Mechanical Engineers (1994-1996)
- Research Associate - Textile Research Institute/Princeton
- Member of the Manufacturing Technology Operating Group of the ASME
- Peer Reviewer for ASME Fellows

Memberships:

- American Society for Engineering Education
- Council of Engineering Deans
- Institute of Industrial Engineers
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- American Conference of Academic Deans
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994,
- President (1996)
- SAMPE - Society for Advanced Materials and Process Engineering
- The Textile Institute

Awards and Honors:

- ASME – Fellow, 1995
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994, President, 1996
- The Textile Institute (United Kingdom) – Fellow, 1992
- Georgia Tech Academy of Distinguished Engineering Alumni, 1999
- Techtextil Innovation Prize, 1993 (Germany)
- ASTM Harold Dewitt Smith Award, 1998

Publications:

"Deductions about the False-Twist Process from Observations of the Variation of Torque on Detwisting at Heat Set Yarn," with Backer, S., and Thwaites, J.J., Journal of the Textile Institute, 67, p. 183-186, 1976.

"Transient Threadline Behavior in False-Twist Texturing," with Thwaites, J.J., and Backer, S., Journal of the Textile Institute, 67, 1976.

"Mechanics of Texturing Thermoplastic Yarns: Part III. Experimental Observations of Torsional Behavior of the Texturing Threadline for Pre-Drawn PET Yarns," with Backer, S., Textile Research Journal, 46, pp. 802-908, 1976.

"Mechanics of Texturing Thermoplastic Yarns: Part V. Steady State Mechanics of Drawing Texturing," Textile Research Journal, 47, p. 256-266, 1977

"Material-Process Interactions During False-Twist Texturing," with Backer, S., Journal of Applied Polymer Science: Applied Polymer Symposium, 31, p. 63-82, 1977.

"Mechanics of Texturing Thermoplastic Yarns: Part VI. Transient Mechanics of Draw Texturing," with Backer, S., Textile Research Journal, 48, p. 198-218, 1978.

"On the Mechanics of Draw Texturing," Journal of Applied Polymer Science: Applied Polymer Symposium, 33, p. 197-202, 1978

"Energy Consumption and Conservation: Textile Drying," ACS Symposium Series, 107/17, 1979

"All That Glitters is Not Gold," Textile World, October 1979

"Energy Conservation in the Textile Industry," ERDA - Phase I Report, DOE, April, 1977, Quarterly Reports, 1976 to 1977, Final Report.

"Processing of Pitch-Based Staple Carbon Fiber," Union Carbide Corporation, November 1977, Final Report.

"Low Thermal Conductivity of PAN-Based Carbon Fiber, Hercules, Inc., Monthly Reports and Final Report

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PATENTS Consisting of Original Contributions to field of engineering:

1. U.S. Patent 4,290,170 "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.
2. U.S. Patent 4,497,866 "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.
3. U.S. Patent 4,602,892 "Sucker Rod," A braided composite rod and coupling for pumping oil.
4. U.S. Patent 4,841,613 "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.
5. U.S. Patent 4,909,127 "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.
6. U.S. Patent 5,004,474 "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.
7. U.S. Patent 5,357,839 "Solid Braid Structure" A 3-D system for producing braids.
8. U.S. Patent 5,358,758 "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.
9. U.S. Patent 5,411,463 "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.
10. U.S. Patent 5,501,133 "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.
11. U.S. Patent 5,697,969 "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

Non-patentable trade secret inventions developed at Albany International Research Co.

1. Fiber-reinforced composite rocket igniter for Small ICBM and Pegasus Air-Launched Vehicle
2. Specialty vascular grafts and bio-absorbable orthopedic implants
3. Flexible air-beam for military structures
4. New method for drying paper during the papermaking process
5. Complex, reduced delamination rocket motor exit cones

EXHIBIT 2

Handbook of technical textiles

Edited by
A R Horrocks and S C Anand



The Textile Institute



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HANDBOOK OF TECHNICAL TEXTILES

Edited by
A R Horrocks and S C Anand



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*To the past and present staff members, support staff and students in
Textile Studies at Bolton Institute, for their friendship and support over
the years.*

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15

Medical textiles

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15.1 Introduction

An important and growing part of the textile industry is the medical and related healthcare and hygiene sector. The extent of the growth is due to constant improvements and innovations in both textile technology and medical procedures. The aim of this chapter is to highlight the specific medical and surgical applications for which textile materials are currently used. A variety of products and their properties that make them suitable for these applications will be discussed.

Textile materials and products that have been engineered to meet particular needs, are suitable for any medical and surgical application where a combination of strength, flexibility, and sometimes moisture and air permeability are required. Materials used include monofilament and multifilament yarns, woven, knitted, and nonwoven fabrics, and composite structures. The number of applications are huge and diverse, ranging from a single thread suture to the complex composite structures for bone replacement, and from the simple cleaning wipe to advanced barrier fabrics used in operating rooms. These materials can be categorised into four separate and specialised areas of application as follows:

- **Nonimplantable materials** – wound dressings, bandages, plasters, etc.
- **Extracorporeal devices** – artificial kidney, liver, and lung
- **Implantable materials** – sutures, vascular grafts, artificial ligaments, artificial joints, etc.
- **Healthcare/hygiene products** – bedding, clothing, surgical gowns, cloths, wipes, etc.

The majority of the healthcare products manufactured worldwide are disposable, while the remainder can be reused. According to a survey in the USA during the decade 1980–1990, the growth of medical textile products occurred at a compound annual rate of 11%. It is estimated that the annual growth was around 10% during 1991–2000. In western Europe the usage of nonwoven medical products between 1970 and 1994 rose from 3000 tonnes to 19700 tonnes¹ (Fig. 15.1). The medical

Table 15.2 Extracorporeal devices

Product application	Fibre type	Function
Artificial kidney	Hollow viscose, hollow polyester	Remove waste products from patients blood
Artificial liver	Hollow viscose	Separate and dispose patients plasma, and supply fresh plasma
Mechanical lung	Hollow polypropylene, hollow silicone, silicone membrane	Remove carbon dioxide from patients blood and supply fresh blood

Table 15.3 Implantable materials

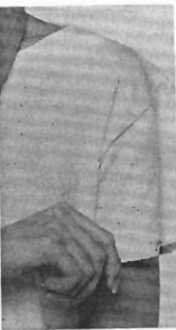
Product application	Fibre type	Manufacture system
Sutures		
biodegradable	Collagen, polylactide, polyglycolide	Monofilament, braided
non-biodegradable	Polyamide, polyester, PTFE, polypropylene, steel	Monofilament, braided
Soft-tissue implants		
artificial tendon	PTFE, polyester, polyamide, silk, polyethylene	Woven, braided
artificial ligament	Polyester, carbon	Braided
artificial cartilage	Low density polyethylene	Nonwoven
artificial skin	Chitin	
eye contact lenses/artificial cornea	Polymethyl methacrylate, silicone, collagen	
Orthopaedic implants		
artificial joints/bones	Silicone, polyacetal, polyethylene	
Cardiovascular implants		
vascular grafts	Polyester, PTFE	Knitted, woven
heart valves	Polyester	Woven, knitted

- 4 The properties of the polymer will influence the success of the implantation in terms of its biodegradability.

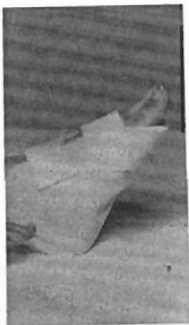
Polyamide is the most reactive material losing its overall strength after only two years as a result of biodegradation. PTFE is the least reactive with polypropylene and polyester in between.²⁴

15.5.2 Sutures

Sutures for wound closure are either monofilament or multifilament threads that are categorised as either biodegradable or nonbiodegradable. Biodegradable sutures are used mainly for internal wound closures and nonbiodegradable sutures are used to close exposed wounds and are removed when the wound is sufficiently healed.



(b)



(d)

on-implantable
e wrist brace,

four key factors
llows:

at which human

han larger fibres

the fibres should
; agents.

EXHIBIT 2

Confidential Videotaped Deposition of:
Dr. David S. Brookstein, Vol. I

July 26, 2006

Page 1

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3 C.A. NO. 04-12457 PBS

4 _____ x
5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

10 A Delaware Corporation,

11 Defendants.
12 _____ x

13 CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

14 DAY 1 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 26, 2006

18
19
20 Reported by:

21
22 PAMELA HARRISON, RMR, CRR, CSR
23
24
25

**READ & SIGN
COPY**

Page 42

1 MR. BONELLA: It assumes -- I am 08:45:58a
2 objecting because of the way you phrased the 08:46:00a
3 question. It assumes facts that aren't -- 08:46:02a
4 haven't been established. 08:46:04a
5 BY MR. SABER: 08:46:06a
6 Q. You can go ahead and answer the 08:46:06a
7 question. 08:46:08a
8 A. This work experience is primarily a 08:46:08a
9 paragraph that I use for when I'm going to give a 08:46:10a
10 paper and ask you for a biosketch. And if I were 08:46:12a
11 to write everything I did on my work experience, 08:46:15a
12 it could be an encyclopedia, so you just pick and 08:46:18a
13 choose. There was no special reason for 08:46:22a
14 anything. 08:46:23a
15 Q. Were vascular prosthesis in orthopedic 08:46:23a
16 implants the primary implantable medical devices 08:46:26a
17 that you worked on in this aspect of your job -- 08:46:31a
18 A. No. 08:46:33a
19 Q. -- in Albany? 08:46:34a
20 A. No, there were no primary. Each one 08:46:35a
21 got my attention. 08:46:37a
22 Q. What kind of suture products did you 08:46:39a
23 work on during this period of time? 08:46:42a
24 A. As I recall, U.S. Surgical at the time 08:46:44a
25 had developed a new resorbable material. I think 08:46:49a

Page 43

1 it was something made from polyglycolic acid, but 08:46:54a
2 I'm not sure. And as part of Albany 08:46:59a
3 International Research Company, we had a fiber 08:47:00a
4 spinning group, and Matt Hermes and a few other 08:47:04a
5 people from U.S. Surgical had approached Albany 08:47:06a
6 to spin the -- make this fiber, and then when the 08:47:09a
7 fiber was made, they said, Well, let's talk to 08:47:12a
8 the guy who runs biomedical devices and see if we 08:47:14a
9 can make sutures. 08:47:17a
10 So I then worked with Hermes 08:47:18a
11 and other people who I don't recall at U.S. 08:47:20a
12 Surgical to come up with a braided structure. 08:47:23a
13 Q. That's because you were an expert on 08:47:30a
14 braiding? 08:47:31a
15 A. I assume that's why they came to me. 08:47:32a
16 Q. Right. Beyond -- how long did that 08:47:35a
17 project last? 08:47:47a
18 A. I don't recall. That was -- 08:47:48a
19 Q. Can you give me any sort of an 08:47:50a
20 approximation? 08:47:52a
21 A. Two, three years. But, you know, I 08:47:52a
22 want to be able to -- if this becomes important, 08:47:54a
23 I want to be able to go back and look. I -- this 08:47:57a
24 is over 15 years ago. I don't -- over almost 20 08:48:00a
25 years ago, I don't recall. We had many projects. 08:48:04a

Page 44

1 Q. You anticipated my next question, 08:48:06a
2 which is, about when did this occur? 08:48:08a
3 A. Well, of course, yes. I don't recall 08:48:10a
4 exactly. 08:48:12a
5 Q. 15, 20 years ago, is that -- I mean, 08:48:12a
6 is that a ballpark? 08:48:15a
7 A. Yes. 08:48:17a
8 Q. Okay. 08:48:19a
9 A. Well, it certainly occurred later than 08:48:19a
10 12 years ago when I went to work for Philadelphia 08:48:23a
11 University, but I don't recall when. 08:48:25a
12 Q. Right. Other than that project, did 08:48:31a
13 you have any other projects in this period of 08:48:34a
14 time that involved suture? 08:48:35a
15 A. You know, I don't recall. I know that 08:48:39a
16 occasionally we would use something called IR&D 08:48:41a
17 money, internal research and development money, 08:48:44a
18 and it is possible that I looked at things 08:48:47a
19 involving sutures that might -- I could then go 08:48:51a
20 out and go to industry and say, Look, we're an 08:48:53a
21 expert on that; but there's no way I have of 08:48:57a
22 recalling, remembering of that. 08:49:00a
23 But it was common practice that 08:49:01a
24 when we had various practice fields, that we 08:49:02a
25 also would use IR&D money, internal research 08:49:05a

Page 45

1 and development money, to do further 08:49:08a
2 development work, but I don't recall any 08:49:10a
3 details. 08:49:11a
4 Q. Okay. How many projects did you work 08:49:12a
5 on that had to do with vascular prostheses? 08:49:16a
6 A. At least one. We were contracted by 08:49:25a
7 Meadox Medical, which is now part of Boston 08:49:30a
8 Scientific, and, you know, I don't know if it was 08:49:33a
9 a group of projects or it was all one umbrella 08:49:41a
10 project, I'd have no way of knowing. 08:49:45a
11 I know we got a patent on 08:49:46a
12 something we did, but that's -- it was one 08:49:49a
13 patent, but that's all I remember. 08:49:51a
14 Q. Yeah. Do you recall any other 08:49:55a
15 projects having to do with vascular prostheses? 08:49:56a
16 A. No. 08:50:01a
17 Q. How about orthopedic implants; how 08:50:02a
18 many projects on orthopedic implants? 08:50:07a
19 A. We did work for a company called 08:50:11a
20 Acufex, A-C-U-F-E-X, which at the time was owned 08:50:13a
21 by American Cyanamid, later became part of Smith 08:50:17a
22 & Nephew, and there were a variety of projects 08:50:22a
23 involving resorbable bone plates, resorbable bone 08:50:25a
24 screws, things of that nature. 08:50:29a
25 But I don't know, was it three 08:50:32a

12 (Pages 42 to 45)

Page 58

1 described applied to your work that led to the 09:04:05a
 2 '969 patent? 09:04:07a
 3 A. That is correct. 09:04:08a
 4 Q. Okay. Now, on Page 2 -- 09:04:09a
 5 A. Of what? 09:04:16a
 6 Q. Of your -- I'm going back to 09:04:17a
 7 Exhibit-198 now, your first report. 09:04:19a
 8 A. Yeah. 09:04:21a
 9 Q. You list a series of articles. 09:04:22a
 10 A. Right. 09:04:25a
 11 Q. Publications -- 09:04:26a
 12 A. Yes. 09:04:29a
 13 Q. -- I should say. 09:04:29a
 14 Do any of these publications 09:04:31a
 15 have to do with suture? 09:04:33a
 16 A. Not that I can recall. 09:04:35a
 17 Q. Now, in your -- 09:04:37a
 18 A. Well, other than -- 09:04:38a
 19 Q. Okay. 09:04:40a
 20 A. Other than -- we have on the 09:04:40a
 21 mechanical properties a three-dimensional -- you 09:04:45a
 22 know, no, the answer is no. 09:04:50a
 23 What I was going to say is 09:04:51a
 24 multilayer interlock braided and this patent 09:04:53a
 25 you've asked me is about multilayer interlock 09:04:59a

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1 braided and since it did mention sutures in 09:05:02a
 2 here, you could draw some kind of obtuse 09:05:05a
 3 line -- 09:05:07a
 4 Q. Right. 09:05:07a
 5 A. -- but I've already, I think, 09:05:07a
 6 demonstrated that I was not involved in that part 09:05:09a
 7 of the inventive thing here. 09:05:11a
 8 So to go back to your question, 09:05:12a
 9 the answer is no. 09:05:14a
 10 Q. Okay. Okay. 09:05:15a
 11 A. Except -- except -- for the last paper 09:05:18a
 12 that I've published on physical properties of 09:05:21a
 13 twisted structures, that is a paper that I 09:05:23a
 14 collaborated with Professor Ning Pan at the 09:05:28a
 15 University of California in Davis, and that's a 09:05:31a
 16 very technical paper on textile linear 09:05:34a
 17 structures. And when it's all said and done, one 09:05:39a
 18 of the things that a suture is is a textile 09:05:43a
 19 linear structure. 09:05:47a
 20 So one -- while sutures might not 09:05:48a
 21 have been mentioned in that paper, a lot of what 09:05:51a
 22 is looked at in the art of linear structures by 09:05:53a
 23 someone who's expert in the field of linear 09:05:59a
 24 structures, of which I represent myself as, one 09:06:02a
 25 could then possibly use material that was in that 09:06:05a

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1 paper to opine on things that were associated with 09:06:08a
 2 sutures. 09:06:12a
 3 Q. Okay. 09:06:12a
 4 A. At some point today I suspect we're 09:06:13a
 5 going to talk about bending rigidity and we will 09:06:16a
 6 find that when I opine on bending rigidity, 09:06:19a
 7 you'll see how I've been able to study that area 09:06:24a
 8 over a period of time and be able to opine on 09:06:27a
 9 things associated with sutures. These are all 09:06:30a
 10 connected in the body of art. 09:06:33a
 11 So physical properties of twisted 09:06:36a
 12 structures, one could say, while this -- while 09:06:38a
 13 it's not mentioning sutures in there, it does 09:06:39a
 14 speak to my expertise and my background with 09:06:42a
 15 linear structures of textile materials of which 09:06:49a
 16 sutures are. 09:06:51a
 17 Q. What are other examples of linear 09:06:52a
 18 structures of -- 09:06:57a
 19 A. Okay. 09:07:01a
 20 Q. A suture is one. What are some 09:07:01a
 21 others? 09:07:02a
 22 A. Well, we can go -- we can go to wire 09:07:02a
 23 ropes which I -- you'll see in my patents, I have 09:07:05a
 24 patents on sucker rods which I -- are the rods 09:07:08a
 25 that are used to pump oil from the ground and I 09:07:11a

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1 made braided sucker rods. Ropes, marine ropes. 09:07:13a
 2 The shoelaces. Vascular grafts. The sutures. 09:07:17a
 3 You can look at a whole range of area of braided 09:07:26a
 4 structures that are tensile structures. 09:07:31a
 5 Q. Would prostheses fall into that, or 09:07:34a
 6 not? 09:07:39a
 7 A. From my viewpoint, a prosthesis is 09:07:39a
 8 more looking at holding pressure; it's not there 09:07:44a
 9 for tensile properties, it's more there for 09:07:47a
 10 radial pressure -- or pressure properties. But 09:07:50a
 11 again, I'd have to go back and look at that. 09:07:52a
 12 Q. Okay. Would you consider a prosthesis 09:07:54a
 13 a linear -- 09:07:59a
 14 A. What kind of -- 09:08:00a
 15 Q. Yeah. What was the category that you 09:08:04a
 16 put suture into that this paper had to do with? 09:08:06a
 17 A. Twisted structures. 09:08:08a
 18 Q. Linear twisted structures? 09:08:09a
 19 A. Yes. 09:08:12a
 20 Q. Is a prosthesis a linear twisted 09:08:12a
 21 structure? 09:08:15a
 22 MR. BONELLA: Objection. Asked 09:08:16a
 23 and answered already. 09:08:16a
 24 THE WITNESS: A prosthesis has 09:08:18a
 25 linear twisted structures in it. 09:08:21a

16 (Pages 58 to 61)

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1 that. 09:27:47a
2 BY MR. SABER: 09:27:48a
3 Q. The next item that you do mention is a 09:27:48a
4 master of science in textile technology from MIT? 09:27:51a
5 A. That is correct. 09:27:55a
6 Q. Okay. Did your studies there 09:27:55a
7 specifically involve suture? 09:27:57a
8 A. Again, those studies for my master 09:27:58a
9 were the precursor studies to my doctorate and 09:28:00a
10 that was when I first started to understand about 09:28:02a
11 how heat and pressure and temperature and 09:28:06a
12 stretching affect the transverse properties and 09:28:09a
13 transverse behavior of fibers that are in yarns 09:28:13a
14 that could subsequently be used for sutures, that 09:28:17a
15 is correct. 09:28:19a
16 Q. But were sutures specifically studied 09:28:20a
17 during the course of your studies there? 09:28:23a
18 A. The studies I had for the -- for my 09:28:24a
19 doctorate? I don't recall at the time. 09:28:26a
20 Q. Okay. Let me go to the next item, you 09:28:31a
21 say a bachelor of textile engineering from 09:28:33a
22 Georgia Tech? 09:28:36a
23 A. Yes. 09:28:36a
24 Q. Again, did any of the studies there 09:28:37a
25 specifically involve suture? 09:28:39a

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1 A. Well, at Georgia Tech at the time it 09:28:40a
2 was the only school that was accredited by the 09:28:44a
3 precursor for the engineering -- excuse me, for 09:28:48a
4 -- accreditation for engineering and technology. 09:28:51a
5 The precursor body was the Engineering Council 09:28:54a
6 for Professional Development. And I went there 09:28:58a
7 because I could get a textile degree that also 09:29:00a
8 had engineering. 09:29:04a
9 Within that program there was a 09:29:05a
10 course called Fiber Science, T-4201, which 09:29:07a
11 ironically I taught when I went back as a 09:29:12a
12 teacher. And in 4201 we talked about using 09:29:15a
13 fibers for a variety of different products 09:29:18a
14 including sutures. 09:29:21a
15 So I both took the course and 09:29:22a
16 then I taught the course from '75 to '80 and 09:29:25a
17 sutures was one of the areas in the syllabi. 09:29:29a
18 Q. Sutures was one of the areas that the 09:29:31a
19 textiles -- that the fibers were used that was 09:29:34a
20 discussed in the course? 09:29:36a
21 A. That's correct. 09:29:37a
22 Q. Okay. What other products were 09:29:37a
23 discussed? 09:29:39a
24 A. I don't know. And the only reason why 09:29:39a
25 I remember that is I was -- since we're talking 09:29:41a

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1 about sutures today, I wanted to go back through 09:29:43a
2 my head and think of what we did. 09:29:46a
3 Q. Right. 09:29:48a
4 A. You know. 09:29:48a
5 Q. But it wasn't -- suture was not the 09:29:48a
6 only product that was discussed? 09:29:51a
7 A. Oh, no, not at all. 09:29:52a
8 Q. It was one of about how many products? 09:29:53a
9 A. I have no way of knowing. 09:29:55a
10 Q. Okay. And you had taught this course 09:29:56a
11 subsequently when you were on -- 09:29:58a
12 A. Yes. 09:29:59a
13 Q. When did you teach this course? 09:30:00a
14 A. I taught from '75 to '80 at Georgia 09:30:02a
15 Tech in the textile engineering program. 09:30:05a
16 Q. And this was -- and again, suture was 09:30:06a
17 one of the products that was mentioned -- 09:30:09a
18 A. That is correct. 09:30:12a
19 Q. -- that these yarns can be used in? 09:30:13a
20 A. That's correct. 09:30:16a
21 So we had a look at suture 09:30:16a
22 properties. 09:30:19a
23 Q. Excuse me? 09:30:19a
24 A. So we looked at suture properties. 09:30:20a
25 Q. As against -- 09:30:23a

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1 A. Again, we're talking 25 years. I just 09:30:23a
2 remember the word sutures. 09:30:25a
3 Q. Right. 09:30:26a
4 A. If you ask me to reconstruct my 09:30:27a
5 lectures or my lecture notes, it would be 09:30:29a
6 impossible. 09:30:31a
7 Q. Right. I just want to make sure that 09:30:32a
8 I understand. It wasn't a class about sutures, 09:30:34a
9 it was a class about fiber science and suture was 09:30:35a
10 one of the -- 09:30:40a
11 A. It was one of the areas. 09:30:40a
12 Q. -- applications? 09:30:40a
13 A. That is correct. 09:30:42a
14 Q. And approximately how many 09:30:42a
15 applications were discussed? 09:30:43a
16 A. I've already told you I don't remember. 09:30:46a
17 Q. Okay. The next item is your work at 09:30:47a
18 the Harvard Business School summer program? 09:30:50a
19 A. Yes. 09:30:52a
20 Q. And the Harvard Graduate School of 09:30:53a
21 Education? 09:30:55a
22 A. Yes. 09:30:55a
23 Q. Summer program. 09:30:56a
24 Did any of that work involve 09:30:58a
25 suture? 09:31:01a

19 (Pages 70 to 73)

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1 BY MR. SABER: 09:34:33a
 2 Q. Dr. Brookstein, we're going to try and 09:34:33a
 3 avoid that. 09:34:35a
 4 A. Okay. Well, let's see where we go. 09:34:35a
 5 Q. So we don't have an issue. 09:34:36a
 6 A. Let's see where we go. 09:34:37a
 7 Q. Right. 09:34:37a
 8 A. The point is there was a lot of work 09:34:37a
 9 done for U.S. Surgical over a period of several 09:34:40a
 10 years on sutures, so I have to be very careful 09:34:42a
 11 about what I tell you. 09:34:46a
 12 Q. Sure, I understand. I understand your 09:34:46a
 13 point, and we'll try and be sensitive to it. 09:34:48a
 14 A. Okay. Okay. 09:34:51a
 15 MR. BONELLA: I agree to 09:34:51a
 16 disagree on our positions. 09:34:53a
 17 THE WITNESS: And I might add, 09:34:54a
 18 if you start asking me questions about some of 09:34:55a
 19 these other products, I'm going to have to be -- 09:34:57a
 20 I mean, what's in a patent is in a patent, the 09:35:00a
 21 patent is there for public knowledge; but I 09:35:02a
 22 can't get into too many details because the very 09:35:04a
 23 nature of the work that I did for Albany 09:35:06a
 24 International was confidential. 09:35:08a
 25 BY MR. SABER: 09:35:11a

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1 Q. Okay. Let me ask about -- a bit, 09:35:11a
 2 while we're on the topic of the work you did for 09:35:15a
 3 U.S. Surgical -- 09:35:17a
 4 A. Yes. 09:35:18a
 5 Q. -- did any patents come out of that 09:35:18a
 6 work, whether you're named on it or not? 09:35:20a
 7 A. Well, if I was named on it, I would 09:35:23a
 8 know. I don't know -- I don't know what patents 09:35:26a
 9 came or did not come out of it. There would be 09:35:27a
 10 no reason for me to look. Obviously I know every 09:35:30a
 11 patent my name's on. 09:35:34a
 12 Q. Okay. Then let me ask you the 09:35:35a
 13 question this way. Were you named on any patents 09:35:36a
 14 that came out of the work you did for U.S. 09:35:40a
 15 Surgical? 09:35:42a
 16 A. I would have -- again -- 09:35:43a
 17 Q. Are you named? 09:35:45a
 18 A. Not that I know of, no. 09:35:45a
 19 Q. You would know if you were named, 09:35:47a
 20 correct? 09:35:49a
 21 A. I would know if I was named. 09:35:49a
 22 Q. Right. And -- 09:35:50a
 23 A. But as we know -- or, no, let me back 09:35:52a
 24 off. 09:35:54a
 25 I know that there are 09:35:54a

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1 organizations that are sometimes lackadaisical 09:35:57a
 2 about inventorship, which, as you know, can make 09:36:03a
 3 a patent invalid. And I don't know if -- because 09:36:07a
 4 I've never read the U.S. Surgical patents. If I 09:36:10a
 5 read those U.S. Surgical patents, I might be able 09:36:13a
 6 to say, I invented that, but I've never read 09:36:15a
 7 them. 09:36:21a
 8 Q. Sir, all I want to know is, with 09:36:21a
 9 respect to the work that you did in connection 09:36:23a
 10 with U.S. Surgical, were you a named inventor on 09:36:25a
 11 any patents? 09:36:29a
 12 A. I already answered that. No. 09:36:30a
 13 Q. And were you named as an inventor on 09:36:32a
 14 any application that came out of the work you did 09:36:35a
 15 for U.S. Surgical? 09:36:39a
 16 A. I would have no way of knowing that 09:36:39a
 17 because when I do a search, the search is only 09:36:41a
 18 for inventorship. I don't know a process for 09:36:43a
 19 searching for applications. So there could be, 09:36:48a
 20 there could not be; I have no way of knowing 09:36:50a
 21 that. 09:36:52a
 22 Q. Do you recall whether anyone, in 09:36:52a
 23 connection with your work at U.S. Surgical -- for 09:36:55a
 24 U.S. Surgical, whether anyone asked you to sign 09:36:58a
 25 any papers in connection with a patent 09:37:01a

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1 application? 09:37:04a
 2 A. I don't recall. I know I signed a 09:37:04a
 3 confidentiality agreement, but I don't know. 09:37:06a
 4 Q. No one ever asked you, that you can 09:37:07a
 5 recall, and asked you to sign as an inventor for 09:37:09a
 6 a patent application in relationship to this 09:37:12a
 7 world? 09:37:18a
 8 A. I can't recall that. I can't recall 09:37:18a
 9 that. I regularly did that, but I can't recall. 09:37:20a
 10 Q. Right. The -- could you describe in a 09:37:23a
 11 -- just in a general way what the work that you 09:37:28a
 12 did while at Albany for U.S. Surgical, what it 09:37:32a
 13 involved? 09:37:34a
 14 A. In a general way. 09:37:35a
 15 Q. Yes, sir. 09:37:38a
 16 A. Okay. U.S. Surgical wanted a 09:37:39a
 17 resorbable suture. Okay. To go from a fiber to 09:37:42a
 18 a suture is a long, arduous scientific and 09:37:48a
 19 engineering process. It was my job, that I can 09:37:53a
 20 recall, to look and measure the fiber properties, 09:37:55a
 21 the tensile properties, the transverse 09:37:59a
 22 compressive properties, lubricity, things of that 09:38:02a
 23 nature, and then begin to do calculations and 09:38:06a
 24 determinations as to what would offer the best 09:38:10a
 25 structure that would then subsequently give 09:38:14a

21 (Pages 78 to 81)

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1 properties that would be advantageous to this 09:38:18a
 2 particular suture. 09:38:21a
 3 So I then -- as a fiber 09:38:22a
 4 scientist first, I would then measure and 09:38:24a
 5 calculate what the fiber properties were, okay; 09:38:28a
 6 then, using my knowledge of textile linear 09:38:32a
 7 structures, I could then determine what the 09:38:35a
 8 proper braid angle would be that would reduce 09:38:40a
 9 to a given modulus, a given strength, a given 09:38:43a
 10 knot -- given tensile strength, a given knot 09:38:48a
 11 strength, the whole range of critical suture 09:38:49a
 12 parameters, okay, I could make those calculations. 09:38:52a
 13 Based on those calculations, by 09:38:54a
 14 looking at the science of textile linear 09:38:56a
 15 structures, I could then decide, all right, we 09:39:00a
 16 should try to braid a particular angle, a 09:39:02a
 17 particular linear density, a particular structure. 09:39:06a
 18 I then went back and as an expert 09:39:10a
 19 in textile testing could then go back and then in 09:39:12a
 20 our laboratories test those products for the 09:39:17a
 21 processes -- for the parameters such as tension, 09:39:20a
 22 knot strength, bending rigidity, what have you, I 09:39:23a
 23 could do that. 09:39:29a
 24 And then it's a closed loop 09:39:29a
 25 system. When you're an engineering scientist, 09:39:31a

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1 it's a closed loop. So you would take those 09:39:33a
 2 properties and rarely you would hit what you 09:39:35a
 3 wanted at first and then you'd go back and you'd 09:39:38a
 4 do theoretical analysis, which I did, of the 09:39:40a
 5 sutures, and use my braiding expertise, along 09:39:43a
 6 with my tensile structures expertise, along 09:39:46a
 7 with my suture expertise to go back and in a 09:39:49a
 8 closed loop then say, all right, let's try this. 09:39:52a
 9 Occasionally I would then go to our 09:39:54a
 10 group that spun the fibers and say, You know, 09:39:55a
 11 you're giving me a fiber that has a particular 09:39:58a
 12 modulus and I think I could get a better suture 09:40:03a
 13 with a little lower modulus. Could you alter the 09:40:05a
 14 molecular weight, could you alter the degree of 09:40:10a
 15 stretching, could you alter the thermal treatment? 09:40:12a
 16 He would do that. I would then measure it, make 09:40:14a
 17 my calculations, then go through this iterative 09:40:17a
 18 process of design, engineering, testing, and 09:40:20a
 19 evaluation. And this took place over several 09:40:22a
 20 years. 09:40:24a
 21 Q. Right. 09:40:26a
 22 A. So the point I want to make is I was 09:40:26a
 23 fully involved -- this was a very -- this was a 09:40:28a
 24 very expensive process, as I recall, from U.S. 09:40:31a
 25 Surgical's viewpoint. They wanted to get into 09:40:33a

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1 this market and they said to me, You know, 09:40:39a
 2 Brookstein, your job is to engineer this suture 09:40:39a
 3 using these polymers that we're going to give 09:40:41a
 4 you. And so I had to do the whole range of 09:40:44a
 5 evaluation and theoretical calculation and 09:40:46a
 6 testing. 09:40:50a
 7 Q. Do you -- 09:40:51a
 8 A. It was a very intense process. 09:40:51a
 9 Now, I'm not going to tell you 09:40:53a
 10 what I did on each step because that's the 09:40:54a
 11 confidential part. 09:40:57a
 12 Q. The -- do you know whether U.S. 09:40:58a
 13 Surgical came out with a commercial product -- 09:41:00a
 14 A. I have no idea. 09:41:02a
 15 Q. -- out of this work? 09:41:02a
 16 A. I have no idea. 09:41:03a
 17 Q. You don't know one way or the other? 09:41:04a
 18 A. No, because I would go on to the next 09:41:06a
 19 project. 09:41:08a
 20 Q. Do you know whether this suture was an 09:41:08a
 21 absorbable or a non-absorbable suture? 09:41:13a
 22 A. I recall it was using resorbable 09:41:17a
 23 yarns. 09:41:20a
 24 Q. What do you mean when you say 09:41:20a
 25 resorbable? 09:41:22a

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1 A. That they reabsorbed into the body. 09:41:23a
 2 Q. Okay. Do you know whether it was a 09:41:24a
 3 braided suture? 09:41:25a
 4 A. Well, of course it was a braided 09:41:26a
 5 suture. 09:41:27a
 6 Q. As opposed to a monofilament? 09:41:27a
 7 A. Of course it was a braided suture. 09:41:28a
 8 That's what we -- that's why they came to us. 09:41:30a
 9 Q. Okay. Do you recall who you were 09:41:32a
 10 working with at U.S. Surgical? 09:41:34a
 11 A. Matt Hermes and a name whose -- I seem 09:41:36a
 12 to recall Don Kaplan, but that's all I remember. 09:41:39a
 13 Now, I have to tell you this 09:41:42a
 14 was a big project, they had people from U.S. 09:41:44a
 15 Surgical in and out meeting with us all the 09:41:47a
 16 time. 09:41:49a
 17 Q. Those were the principal people that 09:41:50a
 18 you remember? 09:41:51a
 19 A. They're the names I can remember. I'm 09:41:51a
 20 not -- 09:41:53a
 21 Q. Right. 09:41:53a
 22 A. I wouldn't -- I don't know what -- I 09:41:53a
 23 don't know how to define it as principal. 09:41:54a
 24 Q. Right. 09:41:55a
 25 A. But we've had -- you know, they were 09:41:56a

22 (Pages 82 to 85)

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1 just in -- outside of New Haven and we were up in 09:41:57a
 2 Mansfield, Massachusetts, and there was a shuttle 09:42:00a
 3 going back and forth because this was such a 09:42:03a
 4 complex iterative process of developing this new 09:42:06a
 5 structure. 09:42:09a
 6 Q. I just want to -- the people that you 09:42:09a
 7 remember working with at U.S. Surgical were- 09:42:11a
 8 Dr. Hermes and, is it Dr. Kaplan or Mr. Kaplan? 09:42:14a
 9 A. I don't remember. 09:42:17a
 10 Q. Do you know whether they were the 09:42:20a
 11 principal people involved at U.S. Surgical? 09:42:21a
 12 A. I already said I don't remember. 09:42:23a
 13 Q. Do you recall any other people at U.S. 09:42:24a
 14 Surgical? 09:42:26a
 15 A. I already said I don't remember. 09:42:26a
 16 Q. Okay. Does the name Mr. Chesterfield 09:42:27a
 17 ring a bell? 09:42:31a
 18 A. I don't remember that name. 09:42:32a
 19 Q. How about a Mr. Koyfman; does that 09:42:33a
 20 ring a bell? 09:42:41a
 21 A. I don't remember. 09:42:41a
 22 Q. Okay. The -- going back to Paragraph 09:42:42a
 23 12 on Exhibit-198, where I was asking you about 09:42:44a
 24 the sentence While at Albany, I researched, 09:42:48a
 25 developed, tested, et cetera. 09:42:51a

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1 A. Mm-hmm. 09:42:53a
 2 Q. Does any of the work that you did on 09:42:54a
 3 the materials mentioned in this sentence allow 09:42:59a
 4 you -- or do you believe that it's relevant to 09:43:03a
 5 your work on this case and your testimony and 09:43:08a
 6 your opinions in this case? 09:43:10a
 7 A. The sentence While at Albany, I 09:43:12a
 8 researched, developed, tested, and evaluated 09:43:14a
 9 numerous braided and biomedical implants, that 09:43:18a
 10 clause clearly says, yes, that's what I did. I 09:43:22a
 11 just mentioned some of the areas, but I didn't 09:43:25a
 12 mention all the areas for confidentiality 09:43:27a
 13 reasons. 09:43:29a
 14 Q. Okay. 09:43:29a
 15 A. But I researched, developed, tested, 09:43:30a
 16 and evaluated numerous -- a universe of braided 09:43:32a
 17 and woven biomedical implants. 09:43:37a
 18 Q. Is your work with respect to woven ACL 09:43:40a
 19 prostheses, is it relevant to your work that 09:43:43a
 20 you've done in this case? 09:43:48a
 21 A. You know, I don't know what you mean 09:43:49a
 22 by relevant. I mean, I'm -- it -- I don't know 09:43:50a
 23 how to answer that question. 09:43:53a
 24 Q. Okay. Let me try and be more specific. 09:43:54a
 25 A. Yeah. 09:43:56a

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1 Q. I mean, was the experience that you 09:43:57a
 2 gained from the work you did on woven ACL 09:43:59a
 3 prostheses, did it play a role in any of the work 09:44:03a
 4 you did for this case and opinions you've 09:44:08a
 5 rendered for this case? 09:44:10a
 6 A. Oh. I'll tell you what, yes. 09:44:10a
 7 Remember at one point -- I'm trying to indicate 09:44:12a
 8 to you that I'm an expert in testing, which plays 09:44:15a
 9 a very important role in this program. 09:44:18a
 10 Q. Okay. 09:44:20a
 11 A. A lot of the tensile testing and 09:44:21a
 12 various physical properties testing you do of the 09:44:25a
 13 materials and that you do of the structures for 09:44:28a
 14 any of these products is transferable no matter 09:44:32a
 15 what product you're doing. For instance, a 09:44:36a
 16 tensile test, you would do a tensile test on an 09:44:38a
 17 ACL. Okay? Obviously the ACL is going to have 09:44:42a
 18 different properties than a braid, but you become 09:44:44a
 19 an expert in tensile testing of biomedical 09:44:50a
 20 products and how to evaluate those test results. 09:44:54a
 21 Q. Okay. Beyond testing, is there any 09:44:56a
 22 other information from your work on these various 09:44:59a
 23 products that you believe is helpful to you in 09:45:03a
 24 your opinions? 09:45:07a
 25 A. No, I'd have to go back and look and 09:45:08a

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1 see what I did on those -- I don't recall. 09:45:10a
 2 There's no way I could answer that in a short 09:45:13a
 3 period of time. I'd have to go back and think 09:45:15a
 4 about each one of those projects. 09:45:18a
 5 Q. Okay. You go on and say you taught 09:45:20a
 6 textile engineers at the undergraduate and 09:45:21a
 7 graduate level at Philadelphia University -- 09:45:23a
 8 A. That is correct. 09:45:25a
 9 Q. -- right? 09:45:25a
 10 Materials involved in the 09:45:25a
 11 design, construction, braiding, manufacturing, 09:45:26a
 12 processing of textile structures that include 09:45:28a
 13 braids. Correct? 09:45:35a
 14 A. That's correct. 09:45:35a
 15 Q. What kind of braids did you teach 09:45:35a
 16 about? 09:45:38a
 17 A. Well, in one of our courses called -- 09:45:38a
 18 it was called Technological Development in 09:45:41a
 19 Textiles, it was a graduate course, and I 09:45:44a
 20 specifically talked about biomedical devices, and 09:45:47a
 21 I specifically talked about sutures. 09:45:49a
 22 And the reason why that all 09:45:51a
 23 happened was -- I don't know if you've been 09:45:52a
 24 following the U.S. textile industry, but 09:45:54a
 25 there's been a precipitous decline in the 09:45:57a

23 (Pages 86 to 89)

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1 commodity part of the industry, and as a 09:46:01a
 2 leader of textile engineering education in 09:46:01a
 3 this country, I thought it was important that 09:46:03a
 4 the new students that are coming through 09:46:05a
 5 become expert in what we would call technical 09:46:06a
 6 textiles, of which -- sutures are technical 09:46:09a
 7 textiles. 09:46:13a
 8 So in my course Technological 09:46:13a
 9 Development in Textiles and related areas, we 09:46:15a
 10 covered sutures as one of the areas, and I 09:46:19a
 11 drew on my background and what was in the 09:46:21a
 12 literature as to what was going on in the 09:46:23a
 13 suture world. 09:46:25a
 14 Q. Beyond that one course, did sutures -- 09:46:28a
 15 was sutures, or at least in the aspect of that 09:46:30a
 16 one course, did you teach about sutures in any 09:46:34a
 17 other courses? 09:46:37a
 18 A. I taught a course called Quality 09:46:38a
 19 Assurance, and we -- and sutures was one of the 09:46:41a
 20 areas that we covered. That was in the middle 09:46:43a
 21 '90s. I also taught courses to freshmen about 09:46:45a
 22 all the different structures of textiles, and 09:46:48a
 23 sutures was covered in that area, yes. 09:46:51a
 24 Q. Did you teach any courses that were 09:46:53a
 25 specifically about sutures? 09:46:56a

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1 A. What do you mean by specifically? The 09:46:58a
 2 whole course was about sutures? 09:47:01a
 3 Q. Or a substantial portion of the course 09:47:02a
 4 was about sutures. 09:47:04a
 5 A. I don't -- 09:47:06a
 6 MR. BONELLA: Object to the form 09:47:06a
 7 of the question. 09:47:06a
 8 THE WITNESS: With technical 09:47:07a
 9 textiles, sutures is part of that. I don't 09:47:08a
 10 think we spent 14 weeks ever discussing sutures, 09:47:11a
 11 no. 09:47:15a
 12 BY MR. SABER: 09:47:16a
 13 Q. All right. I mean, with respect to 09:47:16a
 14 any of these courses that you've described -- 09:47:17a
 15 A. Yes. 09:47:19a
 16 Q. -- what's the largest period of time 09:47:19a
 17 in the course that you've spent on sutures? 09:47:21a
 18 A. I have no way of remembering. I don't 09:47:23a
 19 have my syllabi. 09:47:25a
 20 Q. I mean, is this something that was a 09:47:25a
 21 day, something that was three weeks? 09:47:27a
 22 A. It was more than a day and probably 09:47:27a
 23 less than three weeks, but I can't tell you what 09:47:29a
 24 it was. 09:47:32a
 25 Q. Did you have any -- did you teach any 09:47:32a

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1 courses that were specifically on biomedical 09:47:35a
 2 products? 09:47:40a
 3 A. Well, yes, this -- only on biomedical 09:47:41a
 4 products? 09:47:44a
 5 Q. Yes, sir. Yes, sir. 09:47:45a
 6 A. I didn't teach it, but as the dean of 09:47:46a
 7 the School of Engineering and Textiles, it's 09:47:49a
 8 important that our students get that information, 09:47:52a
 9 so I worked with the professors who teach courses 09:47:56a
 10 in biomedical devices in setting up the syllabi 09:48:00a
 11 and making sure that they covered areas such as 09:48:04a
 12 sutures and I would tell them, you know, what it 09:48:06a
 13 is that's important, yes. 09:48:08a
 14 Q. That's just -- but you didn't 09:48:10a
 15 teach the -- what course are you referring to in 09:48:12a
 16 your answer there? 09:48:14a
 17 A. There's a course called biomedical 09:48:15a
 18 either devices or materials. I don't recall the 09:48:18a
 19 actual course name. 09:48:21a
 20 Q. Okay. Okay. But you've never taught 09:48:22a
 21 that course, is that correct? 09:48:23a
 22 A. I have never taught that course, but 09:48:24a
 23 I've supervised the teaching of the course. 09:48:26a
 24 Q. Well, as dean, you supervise the 09:48:27a
 25 teaching of all courses within your department, 09:48:30a

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1 correct? 09:48:33a
 2 A. No, no, no, no. I don't supervise the 09:48:33a
 3 teaching of fashion design courses. 09:48:35a
 4 Q. No, that are within your department. 09:48:36a
 5 A. No, no, no. Fashion design is within 09:48:38a
 6 my department. 09:48:40a
 7 Q. Okay. Is it? 09:48:41a
 8 A. Yeah. 09:48:41a
 9 Q. Okay. 09:48:42a
 10 A. We have the only textile school in the 09:48:42a
 11 world that has fashion design and mechanical 09:48:45a
 12 engineering in it. I keep to my area of 09:48:47a
 13 expertise, which has anything to do with 09:48:49a
 14 engineering textile structures. I don't get 09:48:52a
 15 involved in fashion design. 09:48:54a
 16 Q. Well, I do know a student that's there 09:48:56a
 17 doing fashion design. 09:48:58a
 18 A. Okay. Okay. Well, she's mine. 09:48:59a
 19 Q. What? 09:49:00a
 20 A. She's mine then. 09:49:01a
 21 Q. I guess not because you don't teach 09:49:01a
 22 that either. 09:49:03a
 23 A. No, I didn't say that. She's still 09:49:03a
 24 within my school. 09:49:06a
 25 Q. No, I understand. 09:49:07a

24 (Pages 90 to 93)

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1 The -- beyond what we've 09:49:08a
 2 discussed today -- 09:49:16a
 3 A. Yes. 09:49:18a
 4 Q. -- is there any other expertise -- any 09:49:18a
 5 other work in your background -- 09:49:23a
 6 A. Yes -- 09:49:24a
 7 Q. -- that you've done that specifically 09:49:24a
 8 involved suture? 09:49:29a
 9 A. -- yes, yes. Remember I told you I 09:49:30a
 10 ran the biomedical device group? By the way, 09:49:31a
 11 there's no -- we didn't have official names, but 09:49:34a
 12 that was my responsibility, biomedical devices. 09:49:36a
 13 I regularly attended the 09:49:39a
 14 Society of Biomaterials meetings, Orthopaedics 09:49:42a
 15 Research Society meetings, Radiological 09:49:49a
 16 Society of North America meetings, 09:49:51a
 17 Techtextil -- that's T-E-C-H-T-E-X-T-I-L -- in 09:49:54a
 18 Germany, and there were, on a regular basis, 09:50:00a
 19 programs in biomedical devices and whole-day 09:50:04a
 20 sections on sutures, and since I had done the 09:50:08a
 21 work for U.S. Surgical, I was constantly 09:50:11a
 22 trying to upgrade my background in that area. 09:50:13a
 23 You know, as an educator, we talk 09:50:18a
 24 about that being an engineer requires lifelong 09:50:22a
 25 learning. And just like you attorneys have to 09:50:28a

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1 take continuing education courses, it's very 09:50:30a
 2 important in my field, and any engineering field, 09:50:33a
 3 to stay abreast. So as a result of that, from 09:50:36a
 4 the period of about 1983 even into some times 09:50:38a
 5 when I was at Philadelphia University into the 09:50:43a
 6 mid-'90s, I regularly attended the Society of 09:50:46a
 7 Biomaterials, Orthopaedic Research Society, 09:50:50a
 8 Radiological Society of North America, and 09:50:53a
 9 Techtextil, of which sutures was -- of which 09:50:53a
 10 sutures was an area that was covered. 09:50:56a
 11 So I stayed abreast of the 09:50:58a
 12 field over that period of time because of my 09:51:00a
 13 interest in technical textiles and because of 09:51:01a
 14 my work that I had started with U.S. Surgical. 09:51:04a
 15 Q. Beyond what you've told me, testified -- 09:51:08a
 16 A. Yes. 09:51:10a
 17 Q. -- is there anything else in your 09:51:10a
 18 background that has to do with sutures that we 09:51:12a
 19 haven't discussed today? 09:51:16a
 20 A. I would argue that the entire area of 09:51:17a
 21 textile linear structures, sutures is a subset of 09:51:20a
 22 it, yes. 09:51:22a
 23 Q. Okay. The -- when you did the project 09:51:23a
 24 for U.S. Surgical -- 09:51:24a
 25 A. Yes. 09:51:25a

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1 Q. -- can you give me any ballpark as to 09:51:26a
 2 of about what percentage of your time you spent 09:51:29a
 3 on that project as opposed to other 09:51:32a
 4 responsibilities? 09:51:34a
 5 A. There's no way of knowing. 09:51:34a
 6 Q. Can you give me any -- was it more 09:51:35a
 7 than half of your time? 09:51:37a
 8 A. I said there's no way of knowing. 09:51:38a
 9 Q. Do you know whether it's more than 09:51:39a
 10 half or less than half? 09:51:40a
 11 A. There's no way of knowing. 09:51:42a
 12 Q. So you just can't give me any 09:51:42a
 13 approximation? 09:51:44a
 14 A. I -- I don't -- 09:51:45a
 15 Q. You can't give me any approximation at 09:51:45a
 16 all? 09:51:46a
 17 A. No, because it was a long time ago. 09:51:47a
 18 I know that it was consuming 09:51:48a
 19 me. I know I spent many nights working past 09:51:50a
 20 the normal 9:00-to-5:00 time because this was 09:51:55a
 21 a hurry up -- not hurry up, it was a critical 09:51:59a
 22 product for U.S. Surgical and they wanted to 09:52:03a
 23 do as much as they could to get it right, so I 09:52:05a
 24 would -- while I can't recollect, I would 09:52:09a
 25 suspect that there were some periods of time 09:52:13a

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1 when I spent a hundred percent, 120 percent of 09:52:16a
 2 my time on that project. It was consuming. 09:52:19a
 3 It was a lot of work. 09:52:21a
 4 Q. As far as what I asked you, which is 09:52:23a
 5 over the period of time the percentage -- 09:52:25a
 6 A. I can't tell you. There's no way to 09:52:26a
 7 tell you. 09:52:28a
 8 Q. You can't give me any estimation at 09:52:28a
 9 all, is that correct? 09:52:30a
 10 A. Not at all. 09:52:31a
 11 MR. BONELLA: Objection. You 09:52:35a
 12 kind of answered the question. 09:52:37a
 13 BY MR. SABER: 09:52:38a
 14 Q. Could we -- could you turn to Exhibit 09:52:38a
 15 B to Exhibit-198? 09:52:42a
 16 A. B, yes. B, yes. 09:52:44a
 17 Q. It's a list of cases. 09:52:48a
 18 A. Current cases. 09:52:49a
 19 Q. Right. You've testified as an expert 09:52:50a
 20 at trial or deposition within the previous four 09:52:54a
 21 years. 09:52:56a
 22 A. That's correct. 09:52:57a
 23 Q. The group A are the -- first of all, 09:52:59a
 24 is this still an accurate list, is there anything 09:53:02a
 25 else you need to add to it, where you've 09:53:05a

25 (Pages 94 to 97)

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1 the braid. 01:19:14p
2 MR. BONELLA: Okay. Let's get a 01:19:15p
3 complete question. 01:19:16p
4 BY MR. SABER: 01:19:17p
5 Q. Let me rephrase it just to try and 01:19:17p
6 deal with Mr. Bonella's objection. 01:19:19p
7 Could coating permeating the 01:19:21p
8 braid affect the dissimilar yarns having at least 01:19:23p
9 some different properties that contribute to the 01:19:29p
10 overall properties of the braid? 01:19:31p
11 A. If you had full permeation, the braid 01:19:34p
12 -- the yarns would still contribute to the 01:19:38p
13 properties of the braid but then there could be a 01:19:41p
14 problem associated with the fibers slipping by 01:19:43p
15 each other. 01:19:46p
16 Q. Well, under your theory of basic and 01:19:47p
17 novel and of materially affect basic and novel, 01:19:49p
18 why would that affect basic and novel 01:19:56p
19 characteristics? 01:19:58p
20 A. I guess it would not. 01:19:58p
21 Q. Okay. What experience -- have you 01:20:00p
22 ever done this kind of scanning electron 01:20:14p
23 micrograph testing before? 01:20:17p
24 A. 30 years. 01:20:18p
25 Q. You've been doing it for 30 years? 01:20:19p

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1 A. Yes. 01:20:20p
2 Q. Have you ever done it on sutures 01:20:21p
3 before? 01:20:22p
4 A. Not that I can recall. 01:20:23p
5 Q. Have you ever done it to try to 01:20:25p
6 identify whether -- where and whether there is 01:20:28p
7 coating on a structure? 01:20:32p
8 A. Over the 30-year period, very 01:20:33p
9 frequently. 01:20:36p
10 Q. Okay. On what -- on what -- but 01:20:36p
11 you've never done that for a suture, correct? 01:20:39p
12 A. That's correct. 01:20:41p
13 Q. On what materials have you used this 01:20:42p
14 scanning technique to judge where and -- where 01:20:45p
15 and how much coating there is? 01:20:57p
16 A. I've done it on most of the yarns that 01:20:58p
17 are measured in the first and second set -- 01:21:01p
18 excuse me; most of the fibers that are in the 01:21:04p
19 first and second set. I've done it in my work in 01:21:06p
20 composite materials. I've done it in my work in 01:21:09p
21 flexible structures. I've done it, yes. 01:21:11p
22 Q. Have you done it on braided 01:21:16p
23 structures? 01:21:18p
24 A. Yes. 01:21:18p
25 Q. Have you done it for the purpose of 01:21:19p

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1 trying to understand whether the coating is on 01:21:20p
2 the surface of the braided structure or permeates 01:21:24p
3 the braided structure? 01:21:27p
4 A. Yes, I have. 01:21:28p
5 Q. Okay. Which specific materials have 01:21:29p
6 you done that for? 01:21:31p
7 A. I've done it -- I did it with a 01:21:32p
8 project that's listed in my CV, it was a 01:21:34p
9 non-patented product, I made an air beam for the 01:21:37p
10 Army, and that was a braided structure, and we 01:21:42p
11 applied a coating, and I had to see to what 01:21:45p
12 extent the coating would -- was permeating and 01:21:48p
13 how that would affect the properties of the air 01:21:52p
14 beam. 01:21:53p
15 Q. What was the air beam made of? 01:21:53p
16 A. I don't recall. 01:21:57p
17 What fibers? 01:21:58p
18 Q. Yes, sir. 01:21:59p
19 A. I don't recall. 01:22:00p
20 Q. What's an air beam? 01:22:01p
21 A. An air beam is a braided structure 01:22:02p
22 that's used to -- like an intertube, if you 01:22:05p
23 will. It's 180 -- roughly 180 degrees, it's 01:22:10p
24 pumped up with air, and it replaces steel in the 01:22:14p
25 military structure. 01:22:19p

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1 Q. In what kind of military structure? 01:22:20p
2 A. Hangars, tents, things like that. 01:22:21p
3 Q. Other than the experience with the air 01:22:26p
4 beam, have you done this test on other braided 01:22:35p
5 structures to see where the coating exists and 01:22:38p
6 whether it permeated the braided structure? 01:22:42p
7 A. Yes. I had a project many years ago 01:22:45p
8 making truss cords for the Army, and we were 01:22:46p
9 impregnating, putting resin on, and I had to 01:22:51p
10 determine to what extent the resin went through 01:22:55p
11 the structure. 01:22:57p
12 Q. What's a truss cord? 01:23:03p
13 A. It's a structural member for a bridge. 01:23:05p
14 Q. Do you know what the truss cord was 01:23:09p
15 made of? 01:23:11p
16 A. The fibers were carbon fibers. I 01:23:11p
17 don't recall the resin. 01:23:14p
18 Q. Excuse me? 01:23:15p
19 A. The fibers were carbon fibers. I 01:23:15p
20 don't recall what the resin was, the coating. 01:23:18p
21 Q. And when did you do this -- this test 01:23:23p
22 with the truss cord? About how long ago was 01:23:26p
23 this? 01:23:30p
24 A. 20 years ago. 01:23:32p
25 Q. And how about the air beam one; when 01:23:32p

57 (Pages 222 to 225)

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1 was that? 01:23:34p
 2 A. The air beam was done in the early 01:23:34p
 3 '90s. 01:23:36p
 4 Q. 15 years ago, roughly? 01:23:37p
 5 A. Well, roughly. 01:23:39p
 6 Q. Are there any others? 01:23:47p
 7 A. I indicated it was almost a regular 01:23:51p
 8 practice of mine because I was very involved in 01:23:54p
 9 applying coatings to textile structures and 01:23:56p
 10 seeing to what extent the coating had an effect 01:23:59p
 11 on the structure. 01:24:01p
 12 Q. Can you tell me any others, other than 01:24:01p
 13 the two that you have, where you used this 01:24:03p
 14 scanning electron micrograph technique to see on 01:24:07p
 15 a braided structure where the coating was on the 01:24:14p
 16 braided structure and whether it had permeated 01:24:17p
 17 the braid? 01:24:21p
 18 A. Some of those resorbable plates we did 01:24:21p
 19 for Acufex, they were braided and we had to see 01:24:24p
 20 what -- how much resin was in there. 01:24:28p
 21 Q. And you used the scanning electron 01:24:29p
 22 micrograph? 01:24:34p
 23 A. Always used the scanning electron 01:24:35p
 24 microscope. 01:24:35p
 25 Q. Micrograph is what you had in your 01:24:36p

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1 report. 01:24:39p
 2 A. Micrograph is the picture; microscope 01:24:39p
 3 is the device. 01:24:41p
 4 Q. I got you, okay. 01:24:43p
 5 MR. BONELLA: Just slow down. 01:24:43p
 6 Let him ask the question before you start 01:24:45p
 7 talking even if you know what the question is 01:24:47p
 8 going to be. Just slow down and let him 01:24:49p
 9 finish. Okay? 01:24:51p
 10 BY MR. SABER: 01:24:52p
 11 Q. And what was this product that you 01:24:52p
 12 mentioned, this third one? 01:24:56p
 13 A. I forget where we are. Can you 01:24:58p
 14 repeat? I forget which product. 01:24:59p
 15 Q. For Acufax? 01:25:04p
 16 A. Acufex. 01:25:06p
 17 Q. What kind of product was it? 01:25:07p
 18 A. Resorbable bone plates. 01:25:09p
 19 Q. What's a resorbable bone plate? 01:25:13p
 20 A. It was a device that orthopedic -- an 01:25:17p
 21 orthopedic device manufacturer was making that if 01:25:22p
 22 you had a fracture, you would put that bone plate 01:25:24p
 23 in, in place of a steel bone plate, and as the 01:25:28p
 24 body healed, the bone plate would resorb into the 01:25:31p
 25 body and you'd have the healing. 01:25:34p

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1 Q. And what -- was this a braided 01:25:37p
 2 structure? 01:25:39p
 3 A. Some of them were. 01:25:39p
 4 Q. The ones that you tested with this -- 01:25:40p
 5 with this scanning electron microscope, were 01:25:44p
 6 those braided structures? 01:25:47p
 7 A. Some of them were. 01:25:49p
 8 Q. And do you know what they were made 01:25:50p
 9 of, the braided structures? 01:25:51p
 10 A. No, I don't. 01:25:54p
 11 Q. Any others that you can tell me about? 01:25:54p
 12 A. Not while I'm sitting here. I might 01:26:00p
 13 recall later on. 01:26:02p
 14 Q. Sure. 01:26:03p
 15 Now, on Page 15 of your report, 01:26:04p
 16 Paragraphs 39 and 40, you opine that the coating 01:26:18p
 17 on the micro -- excuse me; on the FiberWire 01:26:28p
 18 suture does not substantially permeate the 01:26:32p
 19 braided structure and does not reside between the 01:26:35p
 20 braid yarns. 01:26:36p
 21 That's your opinion? 01:26:37p
 22 A. That is my opinion. 01:26:38p
 23 Q. And it's also your opinion that the 01:26:39p
 24 coating only appears on the surface of the braid? 01:26:41p
 25 A. That is my opinion. 01:26:44p

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1 Q. Okay. And is that opinion -- are 01:26:45p
 2 those opinions based on anything other than this 01:26:48p
 3 scanning test that we had just been talking 01:26:51p
 4 about? 01:26:55p
 5 A. They're based on the scanning electron 01:26:57p
 6 micrographs, and they're also based on the 01:27:00p
 7 subsequent work I did where I measured the amount 01:27:04p
 8 of coating by weight that was on the FiberWire. 01:27:05p
 9 Q. Well, does the amount of coating by 01:27:09p
 10 weight give you any information as to where the 01:27:12p
 11 coating is on the fiber? 01:27:14p
 12 A. That does not give you information as 01:27:19p
 13 to where it is, it tells you how much it is. 01:27:21p
 14 Q. Right. So that the tests you did on 01:27:23p
 15 the amount of coating don't have any impact on 01:27:25p
 16 your opinions as to whether the coating permeates 01:27:28p
 17 the braided structure or is only on the surface, 01:27:32p
 18 is that correct? 01:27:35p
 19 A. Earlier I said that -- I defined 01:27:37p
 20 permeation as full -- full impregnation of the 01:27:40p
 21 structure. If the weight is on the order that I 01:27:43p
 22 measured, about 4.8 percent, there's no way it 01:27:47p
 23 could fully permeate, there wouldn't be enough 01:27:51p
 24 material in there to do that. So even if it did 01:27:54p
 25 start to go into the structure, there wouldn't be 01:27:55p

58 (Pages 226 to 229)

EXHIBIT 3

LEXSEE 2002 US DIST LEXIS 19039



Cited

As of: Jul 24, 2007

**JAMES A. LIBBEY, et al., Plaintiffs v. WABASH NATIONAL CORPORATION,
Defendant****Docket No. 02-16-P-H****UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE****2002 U.S. Dist. LEXIS 19039****October 7, 2002, Decided**

DISPOSITION: [*1] Defendant's motion to exclude testimony of William English was denied and recommend that its related motion for summary judgment be denied.

CASE SUMMARY:

PROCEDURAL POSTURE: Before the magistrate judge, defendant corporation moved to exclude the testimony of the sole expert witness for plaintiffs, a worker and his wife, in an action alleging product liability arising out of the slip and fall of the worker on the bed of a truck trailer built by the corporation. The corporation also took the position that it was entitled to summary judgment on all claims if the expert's proposed testimony was excluded.

OVERVIEW: The corporation sought to exclude the expert's proposed testimony under Daubert contending that it was unreliable and irrelevant. The corporation contended that the expert exceeded the bounds of his qualifications in attempting to offer opinions as to the proper design of a flatbed trailer, having (a) never worked on such a trailer, (b) never previously inspected such a trailer, (c) no qualifications with respect to the design or manufacture of such a trailer, and (d) no background or experience to allow him to testify as to the efficacy of alternative designs in the context of a flatbed trailer. The expert was to testify that the painted metal surfaces in the trailer bed would have been slippery when wet, that wetness of the trailer bed would have been a normally expected condition, and that the presence of these surfaces contributed significantly to the worker's injuries. The corporation's view of the qualifications required for an

expert was unduly restrictive; the expert's background in slip resistance of metal surfaces was sufficient to qualify him to testify. The corporation's arguments regarding the expert's methodology and relevance of the testimony were meritless.

OUTCOME: The corporation's motion to exclude the expert testimony was denied and the magistrate recommended that its related motion for summary judgment be denied.

LexisNexis(R) Headnotes

Civil Procedure > Summary Judgment > Standards > Genuine Disputes

Civil Procedure > Summary Judgment > Standards > Materiality

[HN1] Summary judgment is appropriate only if the record shows that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. *Fed. R. Civ. P. 56(c)*. In this regard, material means that a contested fact has the potential to change the outcome of the suit under the governing law if the dispute over it is resolved favorably to the nonmovant. By like token, genuine means that the evidence about the fact is such that a reasonable jury could resolve the point in favor of the nonmoving party.

Civil Procedure > Summary Judgment > Burdens of Production & Proof > Movants

Civil Procedure > Summary Judgment > Burdens of Production & Proof > Nonmovants***Civil Procedure > Summary Judgment > Evidence***

[HN2] The party moving for summary judgment must demonstrate an absence of evidence to support the non-moving party's case. In determining whether this burden is met, the court must view the record in the light most favorable to the nonmoving party and give that party the benefit of all reasonable inferences in its favor. Once the moving party has made a preliminary showing that no genuine issue of material fact exists, the nonmovant must produce specific facts, in suitable evidentiary form, to establish the presence of a trialworthy issue. As to any essential factual element of its claim on which the non-movant would bear the burden of proof at trial, its failure to come forward with sufficient evidence to generate a trialworthy issue warrants summary judgment to the moving party.

Evidence > Testimony > Experts > Admissibility***Evidence > Testimony > Experts > Qualifications***

[HN3] *Fed. R. Evid. 702* imposes an important gatekeeper function on judges by requiring them to ensure that three requirements are met before admitting expert testimony: (1) the expert is qualified to testify by knowledge, skill, experience, training, or education; (2) the testimony concerns scientific, technical, or other specialized knowledge; and (3) the testimony is such that it will assist the trier of fact in understanding or determining a fact in issue.

Evidence > Testimony > Experts > Daubert Standard Torts > Negligence > Proof > Custom > Expert Testimony

[HN4] To disallow expert testimony because there are no industry standards applicable to the precise mechanism of injury in a given case would prevent expert testimony in any case involving an injury that had not been anticipated or otherwise addressed by the industry involved. Such an irrational outcome is not contemplated by *Daubert* or *Kumho*.

COUNSEL: For JAMES A LIBBEY, ANN LIBBEY, plaintiffs: DORT S. BIGG, ESQ., W. WRIGHT DANENBARGER, ESQ., WIGGIN & NOURIE, MANCHESTER, NH.

For WABASH NATIONAL CORPORATION, defendant: HAROLD J. FRIEDMAN, MICHELLE ALLOTT, ESQ., FRIEDMAN, GAYTHWAITE, WOLF & LEAVITT, PORTLAND, ME.

JUDGES: David M. Cohen, United States Magistrate Judge.

OPINION BY: David M. Cohen

OPINION***MEMORANDUM DECISION ON DEFENDANT'S MOTION TO EXCLUDE EXPERT TESTIMONY AND RECOMMENDED DECISION ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT***

The defendant, ¹ Wabash National Corporation, moves to exclude the testimony of the plaintiffs' sole expert witness in this action alleging product liability arising out of the slip and fall of plaintiff James A. Libbey on the bed of a truck trailer built by the defendant. The defendants also take the position that they are entitled to summary judgment on all claims if the expert's proposed testimony is excluded. Defendant Wabash National Corporation's Motion to Exclude Expert Testimony of William English and/or For Summary Judgment, etc. ("Motion") (Docket No. [*2] 10). I recommend that the court deny the motions.

1 A second defendant named in the complaint, Lease Plan U.S.A., Inc., has been dismissed from this action by stipulation. Docket No. 9.

I. Summary Judgment Standard

[HN1] Summary judgment is appropriate only if the record shows "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Fed. R. Civ. P. 56(c)*. "In this regard, 'material' means that a contested fact has the potential to change the outcome of the suit under the governing law if the dispute over it is resolved favorably to the nonmovant. By like token, 'genuine' means that 'the evidence about the fact is such that a reasonable jury could resolve the point in favor of the nonmoving party.'" *Navarro v. Pfizer Corp.*, 261 F.3d 90, 93-94 (1st Cir. 2001) (quoting *McCarthy v. Northwest Airlines, Inc.*, 56 F.3d 313, 315 (1st Cir. 1995)). [HN2] The party moving for summary judgment must demonstrate an absence [*3] of evidence to support the nonmoving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986). In determining whether this burden is met, the court must view the record in the light most favorable to the nonmoving party and give that party the benefit of all reasonable inferences in its favor. *Nicolo v. Phillip Morris, Inc.*, 201 F.3d 29, 33 (1st Cir. 2000). Once the moving party has made a preliminary showing that no genuine issue of material fact exists, the nonmovant must "produce specific facts, in suitable evidentiary form, to establish the presence of a trialworthy issue." *Triangle*

Trading Co. v. Robroy Indus., Inc., 200 F.3d 1, 2 (1st Cir. 1999) (citation and internal punctuation omitted); *Fed. R. Civ. P. 56(e)*. "As to any essential factual element of its claim on which the nonmovant would bear the burden of proof at trial, its failure to come forward with sufficient evidence to generate a trialworthy issue warrants summary judgment to the moving party." *McCrory v. Spigel (In re Spigel)*, 260 F.3d 27, 31 (1st Cir. 2001) (citation and internal punctuation omitted).

II. Factual Background

[*4] The parties dispute almost every factual statement included in their opponents' statements of material facts submitted pursuant to this court's Local Rule 56. The following facts provide the necessary setting for the resolution of the pending motion and do not appear to be in dispute.

The defendant, a Delaware corporation with a principal place of business in Indiana, manufactured a truck trailer on which plaintiff James A. Libbey was working on January 26, 2001 in Biddeford, Maine when he slipped and fell. Complaint (Docket No. 1) PP2, 6, 9-10; Answer (Docket No. 2) PP2, 6, 9-10.² There were two painted metal strips in the bed of the trailer which were the longitudinal structural members of the chassis and the support for the wood decking that constituted the remainder of the truck bed; the wood decking was positioned so that the top flanges of the metal I-beams would be flush with the deck surface. Plaintiffs' Statement of Additional Facts ("Plaintiffs' SMF"), included in Plaintiffs, [sic] James A. Libbey and Ann Libbey's Response to Defendant's Statement of Facts and Additional Facts, etc. ("Plaintiffs' Responsive SMF") (Docket No. 18) at 5-17, P54; Defendant Wabash National [*5] Corporation's Response to Plaintiffs' Statement of Additional Facts ("Defendant's Responsive SMF") (Docket No. 23) P54.

2 The defendant denies the allegations in paragraph 10 of the complaint and responds that it has insufficient information "to form a belief as to the allegations made" in paragraph 9 of the complaint. However, neither party provides this essential basic information in its statement of material facts. There does not appear to be a serious dispute about the facts alleged in these paragraphs of the complaint and stated here. *See* Motion at 1 (plaintiff fell on January 26, 2001 while working on trailer); Plaintiffs, [sic] James A. Libbey and Ann Libbey's Objection to Defendant Wabash National Corporation's Motion to Exclude Expert Testimony, etc. ("Objection") (Docket No. 17) at 1 (plaintiff slipped and fell on January 26, 2001 while unloading trailer).

The plaintiffs have designated William English as their sole expert witness. Motion at 2; Objection at 1; Defendant Wabash National Corporation's [*6] Statement of Undisputed Facts in Support of its Motion in Limine, etc. ("Defendant's SMF") (Docket No. 11) P16; Plaintiffs' Responsive SMF P16. The complaint alleges that the truck trailer bed was defective and unreasonably dangerous due to a design defect, Complaint P8, and that the defendant failed to warn users appropriately, *id.* PP14, 18.

III. Discussion

A. Motion to Exclude Testimony

The defendant seeks to exclude English's proposed testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 143 L. Ed. 2d 238, 119 S. Ct. 1167 (1999), contending that it is unreliable and irrelevant. Motion at 4-6. The parties apparently assume that English will testify in accordance with his written report.³ Specifically, the defendant contends that English "is far exceeding the bounds of his qualifications in attempting to offer opinions with respect to the proper design of a flatbed trailer, having; [sic] (a) never worked on such a trailer, (b) never previously inspected such a trailer, (c) no qualifications with respect to the design [*7] or manufacture of such a trailer, and (d) no background or experience to allow him to testify as to the efficacy of alternative designs in the context of a flatbed trailer." Reply at 2.

3 In its reply memorandum, the defendant asserts that "it is critical to point out that Mr. English's slipometer [sic] readings and supplemental report have not been provided to defense counsel, despite the fact that the testing has [sic] completed on June 10, 2002." Defendant Wabash National Corporation's Reply Memorandum, etc. ("Reply") (Docket No. 22) at 4. This statement apparently refers to testing that took place after the date of the only report of English that appears in the record. Exh. A to Motion, dated January 3, 2002. In the absence of any such report, the court can only evaluate English's possible testimony in the light of the earlier report. In any event, the alleged failure of counsel for the plaintiff to comply with discovery requests is not among the factors to be considered in assessing the admissibility of expert testimony under *Daubert* and *Kumho*.

[*8] English apparently will testify that the painted metal surfaces of the I-beam flanges in the trailer bed would have been slippery when wet, that wetness of the trailer bed would have been a normally expected condi-

tion of operation of the truck and that the presence of these surfaces contributed significantly to the plaintiff's injuries. Letter dated January 3, 2002 from William English to W. Wright Danenbarger ("Report"), Exh. A to Motion, at 2-4. He will also testify that installation of an available slip-resistant surface on the smooth surfaces of the I-beam flanges would have prevented the accident. *Id.* at 4-5.

[HN3] *Federal Rule of Evidence 702* imposes an important gatekeeper function on judges by requiring them to ensure that three requirements are met before admitting expert testimony: (1) the expert is qualified to testify by knowledge, skill, experience, training, or education; (2) the testimony concerns scientific, technical, or other specialized knowledge; and (3) the testimony is such that it will assist the trier of fact in understanding or determining a fact in issue.

Correa v. Cruisers, 298 F.3d 13, 24 (1st Cir. 2002) (citing *Daubert* [*9] and *Kumho*). Here, the defendant contends that English's proposed testimony does not meet the first and third requirements.

The third element addresses the relevance of the proposed testimony. The defendant argues that English's proposed testimony is irrelevant because he did not provide evidence of studies, tests or statistics to support his conclusion that the metal strips in the trailer bed are unreasonably slippery; he acknowledged that there are no standards addressing the degree of slip resistance required for components of trailer beds; he did not inspect the trailer at issue or any similar trailers; he did no research concerning his proposed design alternatives; he had no data concerning falls under similar circumstances; and he does not know "the specifics as to how it is that James Libbey fell." Motion at 8-11. Most of these points go to the weight of English's testimony rather than its relevance. The defendant relies on this court's opinion in *Real v. Mazda Motor of Am., Inc.*, 106 F. Supp.2d 75 (D. Me. 2000), to support its argument, but in that case the proffered expert's testimony was based on assumptions that clearly differed from the circumstances [*10] present at the time of the accident, or on assumptions that were not independently verifiable, *id.* at 77-79. The defendant has made no showing that similar differences exist in this case. [HN4] To disallow expert testimony because there are no industry standards applicable to the precise mechanism of injury in a given case would prevent expert testimony in any case involving an injury that had not been anticipated or otherwise addressed by the industry involved. Such an irrational outcome is not contemplated by *Daubert* or

Kumho. English's proposed testimony is not irrelevant under *Rule 702*.

With respect to the first requirement set forth in *Correa*, the defendant's view of the qualifications required for an expert is, in general, unduly restrictive. English's admitted lack of familiarity with the use, design and manufacture of flatbed trailers does not automatically disqualify him from expressing an expert opinion about the slip resistance of a portion of the surface of the defendant's flatbed trailer design. *See generally Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100-01 (10th Cir. 1991) (expert witness in products liability action not strictly [*11] confined to area of practice but may testify concerning related applications; mechanical engineer with expertise in safe design of farm equipment may testify concerning consumer expectations for farm combine); *Bassett Furniture Indus. of N. Carolina, Inc. v. NVF Co.*, 576 F.2d 1084, 1090-91 (5th Cir. 1978) (expert allowed to testify regarding sanding procedures used in furniture manufacturing although he was not familiar with furniture industry); *Colegrove v. Cameron Mach. Co.*, 172 F. Supp.2d 611, 635-36 (W.D. Pa. 2001) (expert in mechanical engineering with no experience in designing mechanism at issue or with machine on which mechanism operated allowed to testify that condition of mechanism was defective); *Traharne v. Wayne Scott Fetzer Co.*, 156 F. Supp.2d 717, 724 (N.D. Ill. 2001) (failure of expert personally to examine machine at issue goes to weight, not admissibility, of testimony). In this case, English's background in slip resistance of metal surfaces is sufficient to qualify him to testify.

Finally, the defendant attacks English's methodology, contending that his use of a slipmeter of his own design and the lack of a relevant [*12] standard for slipperiness renders his opinions inadmissible. Motion at 11-15. The only report from English that is present in the record does not mention the use of a slipmeter or a degree of slipperiness that is unacceptable. The defendant's statement of material facts includes some references to such testimony during English's deposition. Defendant's SMF PP20-24. The defendant relies solely on an unreported recommended decision in the Southern District of Alabama issued in 1995 to support its argument. Motion at 11-14; *Waters v. Wal-Mart Stores, Inc.*, 1995 U.S. Dist. LEXIS 13359 (S.D. Ala. June 16, 1995). The defendant has provided no indication that the recommended decision was adopted by that court. It is not the practice of this court to rely on such opinions as persuasive authority; even if the practice were otherwise, the facts surrounding the opinion proffered in that case are readily distinguishable from the circumstances present here. In any event, the plaintiff has submitted sufficient evidence concerning the use of the English slipmeter, published studies concerning its use and the existence of standards

of the American National Standards Institute and [*13] OSHA that refers to the English slipmeter to allow English to testify concerning any measurements made with this device. Plaintiffs' SMF PP29-31, 35, 41, 43-44, 48-49, 63-66, 70, 87, 89, 104; Exhs. 11, 15, 20 to Plaintiffs' SMF. Again, the defendant's objections go to the weight of English's testimony rather than to its admissibility.

For the foregoing reasons, the defendant's motion to exclude English's testimony is denied.

B. Motion for Summary Judgment

The defendant's motion for summary judgment is based solely on the absence of expert testimony for the plaintiffs. Motion at 15-17. In light of my ruling above, the asserted basis for the motion for summary judgment does not exist. Accordingly, that motion should be denied as well.

IV. Conclusion

For the foregoing reasons, **I DENY** the defendant's motion to exclude the testimony of William English and

recommend that its related motion for summary judgment be **DENIED**.

NOTICE

*A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which [*14] de novo review by the district court is sought, together with a supporting memorandum and request for oral argument before the district judge, if any is sought, within ten (10) days after being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within ten (10) days after the filing of the objection.*

Failure to file a timely objection shall constitute a waiver of the right to de novo review by the district court and to appeal the district court's order.

Dated this 7th day of October, 2002.

David M. Cohen

United States Magistrate Judge

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation, *et al.*

Defendants.

Civil Action No. 04-12457 PBS

**MEMORANDUM IN SUPPORT OF DEFENDANTS ARTHREX, INC.'S AND
PEARSALLS LTD.'S MOTION FOR SUMMARY JUDGMENT OF NON-
INFRINGEMENT AND IN OPPOSITION TO DEPUY MITEK'S MOTION FOR
SUMMARY JUDGMENT OF INFRINGEMENT**

Dated: April 6, 2007

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that the Court used this same exact language to describe defendants' contention regarding the construction of the basic and novel characteristics. Ex. 1 at 16. Whether one refers to *not* significantly sacrificing the physical properties of the *suture* or of the *constituent elements of the suture*, it does not make a difference. The two statements are synonymous.

Just as with defendants' proposed claim construction, in the Court's construction of the basic and novel characteristics, it is the handleability and pliability of *the suture* that is improved by braiding together two dissimilar yarns. For example, in supporting its claim construction, the Court noted "of significance, the specification states: in view of the deficiencies of the prior art, it would be desirable to prepare *multifilament sutures exhibiting improved pliability and handling properties*." Ex. 1 at 17-18 [italicized emphasis added, underlined emphasis in original.]

Once the basic and novel characteristics of the invention have been defined, the next step is to determine whether coating materially affects those basic and novel characteristics. An effect on the basic and novel characteristics of the claimed invention is "material" if the effect is of importance or of consequence to those of ordinary skill in the art. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). As we show below, the undisputed facts are that coating's affect on suture handleability, and especially knot tie-down, are of importance or of consequence to those of ordinary skill in the art.

As an initial matter, as the Court noted, a finding that an added ingredient materially affects the basic and novel characteristics of a patent can be made, as a matter of law, where the specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect. Ex. 1 at 14 (citing *AK Steel*). On this basis alone, defendants are entitled to summary judgment. The '446 patent first explains that multifilament braided sutures have a need for improved handleability. Ex. 5 at col. 1, ll. 12-28. The first prior

There is nothing unique or unusual about this disclosure. It is entirely consistent with the mountain of evidence presented by defendants -- all of it undisputed -- and it is also entirely consistent with the undisputed fact that FiberWire *is* coated to improve its handleability, including knot-sliding, knot tying and ease of passing through tissue. Ex. 2.¹⁷

IV. CONCLUSION

For all the foregoing reasons, defendants' motion for summary judgment should be granted and DePuy Mitek's motion should be denied.

Dated: April 6, 2007

Respectfully submitted,

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¹⁷ DePuy Mitek relies on two inapposite Federal Circuit cases -- *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349 (Fed. Cir. 2006) and *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004) -- to support its assertion that infringement of a "consisting essentially of" claim is not precluded where an unrecited structure in an accused product is unrelated to the claimed invention. First, DePuy Mitek's reliance on *Conoco* and *Norian* is misplaced because, even as DePuy Mitek admits, the transitional phrase at issue in those cases was *not* "consisting essentially of," rather it was "consisting of," which involves an entirely different legal analysis.

Even assuming DePuy Mitek is relying on *Conoco* and *Norian* to advance some sort of "argument-by-analogy," it is still to no avail. At best, *Conoco* and *Norian* stand for the unremarkable proposition that infringement is not avoided if the added ingredient is *unrelated to the claimed invention*. For example, in *Conoco* and *Norian*, the unrecited structures (*i.e.*, a certain impurity found in lubricants, and a mixing spatula present in a chemical kit, respectively) *were unrelated* to the claimed invention. The facts in this case are *very* different. Here, FiberWire's coating *is directly related* to the basic and novel characteristics of the invention. Even DePuy Mitek admits that FiberWire's coating improves its handleability and knot tie-down characteristics. Thus, any rationale DePuy Mitek may have for relying on *Conoco* and *Norian* quickly falls apart.

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING INVALIDITY OF U.S. PATENT NO. 5,314,446

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his expert report as follows.

I. INTRODUCTION

I have been retained, through Dickstein Shapiro Morin & Oshinsky LLP, as a technical expert by Arthrex, Inc. and Pearsalls, Ltd. (together "Defendants") to review U.S. Patent No. 5,314,446 ("the '446 patent") and certain other materials, and to provide my opinion on issues relating to: i) whether claims of the '446 patent are invalid as anticipated by prior art, ii) whether claims of the '446 patent are invalid as obvious in view of prior art, iii) whether claims of the '446 patent are invalid for not satisfying the written description and/or enablement requirements under 35 U.S.C. § 112 and iv) whether inventions claimed in the '446 patent were actually reduced to practice prior to the February 19, 1992 filing date. From a review of DePuy Mitek's interrogatory answers, I understand that claims 1, 2, 8 and 12 are being asserted against Defendants in this case ("the asserted claims"). I am being compensated at a rate of \$1000.00 per day.

I expect to be called to provide expert testimony at trial regarding opinions formed resulting from my investigation of these issues, any matters set forth in this report, and rebuttal of any matters raised by Plaintiff DePuy Mitek. This report includes my opinions regarding these matters. I specifically reserve the right to formulate and offer additional opinions based on any responsive reports received from DePuy Mitek, or on any additional information that may be provided, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or

during trial. Opinions formed are covered below in Section VI. Documents reviewed and considered are identified in Section III and Ex. 1.

II. SUMMARY OF MY OPINIONS

Based upon my review and consideration of the materials identified in Exhibit 1, it is my opinion that U.S. Patent No. 4,610,688, ("the '688 patent"), when combined with U.S. Patent No. 5,120,802 ("the '802 patent"), and/or the general teachings of the art, includes every limitation of the asserted claims of the '446 patent (i.e., claims 1, 2, 8 and 12), and that there was a motivation or suggestion to make these combinations at the time of the '446 patent inventions.

I understand that DePuy Mitek is asserting in this case that the ultra high molecular weight polyethylene ("UHMWPE"), as used in Arthrex's FiberWire suture, is included in "PE," as claimed in the '446 patent. I disagree with that position, however, in the event that the Court were to determine that UHMWPE does fall within the meaning of PE, as claimed in the '446 patent, then I have comments on several other pieces of prior art that are relevant to the anticipation or obviousness inquiries.

For example, in the event that the claims of the '446 patent are construed by the Court to include UHMWPE, it is my opinion that U.S. Patent No. 5,318,575 ("the '575 patent") includes every limitation of the asserted claims of the '446 patent.

Further, it is my opinion that if the Court were to construe the claims of the '446 patent to include UHMWPE, the combination of UK Patent Application No. 2,218,312A

to Burgess ("the Burgess application") and: i) Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture*, Arch Ophthalmol – Vol. 103, December 1985 ("the Cohan article"); ii) *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* ("the DSM brochure"); and/or iii) either one of U.S. Patent Nos. 4,563,392 or 4,543,286, both to Harpell et al. ("the Harpell patents"), would include every limitation of the asserted claims of the '446 patent and that there was a motivation or suggestion at the time of the '446 patent inventions to make these combinations.

It is also my opinion that regardless of how the claims of the '446 patent are ultimately construed, the '446 patent does not describe UHMWPE or teach how to make a suture with UHMWPE to one of ordinary skill in the art at the time of the '446 patent inventions.

It is also my opinion that since there is no evidence that the heterogeneous braids constructed in February 1989 were sterilized to make surgical sutures, there was no actual reduction to practice of an embodiment meeting every limitation of the claimed inventions. It is further my opinion that due to the many technical problems that persisted throughout the development of the invention, the invention was never actually reduced to practice prior to the filing date of February 19, 1992.

III. REVIEW AND USE OF DOCUMENTS AND OTHER MATERIALS

The documents and things I have reviewed and considered in the preparation of this report are the '446 patent, its prosecution history, Arthrex's responses to DePuy

Mitek's interrogatories, DePuy Mitek's responses to Arthrex's interrogatories, U.S. Patents Nos. 5,318,575; 4,610,688, 5,120,802, the Burgess application, the Cohan article, the DSM brochure, the Harpell patents, various documents of DePuy Mitek and/or Ethicon, Dr. Mark Steckel's laboratory notebook, the deposition testimony of Dr. Mark Steckel and Dennis D. Jamiolkowski and the documents and things identified at Ex. 1. I have also relied upon my experience and well-known principles in the manufacturing and processing fields of fibers that can be used for biomedical applications, and discussions with John Witherspoon, who I understand is a legal expert retained in this case.

IV. QUALIFICATIONS

My qualifications as an expert witness are listed in my Curriculum Vitae attached as Ex. 2.

V. THE '446 PATENT AND PROSECUTION HISTORY

This section discusses the disclosures in the '446 patent claims and specification as filed and its prosecution history as it relates to the issues discussed in this report.

The '446 patent is directed to heterogeneous braids that can be used as a component of either surgical suture or ligatures. Ex. 3 at col. 1, ll. 6-7. The '446 patent describes the benefits of a braided multifilament over a monofilament. Some of those benefits include enhanced pliability, knot security and tensile strength when compared with a monofilament. Ex. 3 at col. 1, ll. 8-10. As the '446 patent describes, the enhanced

pliability of a braided multifilament results from the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament.

The '446 patent then describes that although an improvement over monofilaments, braided multifilaments still presented certain problems since attempts to improve specific properties of the multifilament braids (e.g., through the use of coating) would restrict movement of adjacent filaments of the braid, thus resulting in a braid that behaved more like a monofilament.

The '446 patent then goes on to describe that the prior art attempts to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on braid properties. The specification suggests the use of braided multifilaments made at least in part of fibers composed of highly lubricious polymers as a solution. The specification explains that while such braids will be highly pliable, the specification states that they will also be relatively weak and unusable for most suture applications. Ex. 3 at col. 2, ll. 22-25.

The proposed solution described in the '446 patent is a heterogeneous braid made up of two dissimilar materials. According to the specification, the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The specification also states that the first fiber-forming material is a lubricious material, and that the second fiber-forming material is added for strength. The fact that the first fiber-forming materials are lubricious but weak is

further made clear by the specification which states that “a volume fraction [of lubricating yarns] above about 80% may adversely affect the overall strength of the braid.” As described throughout the specification, there is a tradeoff between the properties of the two materials – one being lubricious but weak, the other being added for strength.

Claim 1 of the '446 patent is to a surgical suture, the surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized and braided construction. Claim 1 also states that at least one yarn from the first set is in direct intertwining contact with a yarn from the second set. Claim 1 also states that each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material and that each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material. Claim 1 further defines the first fiber-forming materials as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE, and further defines the second fiber-forming materials as one of PET, nylon and aramid.

The application for the '446 patent was filed on February 19, 1992, as U.S. Patent Application No. 07/838,511 (“the '511 application”). At the time the '511 application was filed, four inventors were listed – Alastair W. Hunter, Arthur Taylor, Jr., Mark Steckel and Dennis D. Jamiolkowski.

During prosecution of the '511 application, the patent examiner at the U.S. Patent and Trademark Office ("PTO") issued a restriction requirement on July 8, 1992. I understand from Defendants' legal expert that a restriction requirement is issued when the examiner believes that a patent application contains at least two different inventions (e.g., in the case of the '446 patent, a heterogeneous braid and a surgical suture). The applicants must then select one invention which remains in the application.

In issuing the restriction requirement, the patent examiner asserted that the '511 application contained two different inventions – i) a heterogeneous braid and ii) a surgical suture, and that the applicants were required to select one of those two inventions which would remain in the '511 application. The examiner also stated that the heterogeneous braid invention was "an intermediate product [that] is useful to make other than the final product [of a surgical suture]." The examiner then stated that the heterogeneous braid invention was "deemed to be useful as a fishing line." Ex. 4 at 2. The applicants selected the surgical suture inventions (i.e., claims 21-24).

Further, during prosecution of the '511 application, the patent examiner at the U.S. Patent and Trademark Office ("PTO") relied on the Burgess patent application and rejected the then-pending claims (i.e., claims 21-24). The Burgess patent application disclosed a heterogeneous braided fishing line comprised of two dissimilar materials – DYNEEMA (which is a brand name for UHMWPE) and polyester and/or nylon. Ex. 5 at 1-2.

The examiner found that the Burgess application disclosed a braided fishing line made up of two polymers with different properties, and therefore, it was “known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber.” Ex. 4 at 4. The examiner reasoned that it would have been obvious to a person of ordinary skill in the art at the time to use a heterogeneous braid for a suture since: i) braided sutures were, at the time, well known in the art; ii) many of the requirements of sutures were comparable to those of fishing line – strength, low stretchability, etc.; and iii) many of the same materials were used to make both fishing lines and sutures. Ex. 4 at 5.

In response to the rejection based on the Burgess application, Ethicon’s attorney argued that it would be bad to use UHMWPE for a suture because it has low elongation and poor knot strength properties. The Ethicon attorney also asserted that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester and/or nylon – the combination disclosed in the Burgess application - then “he would inevitably design an unacceptable suture,” (Ex. 6 at 3-4) and that the braided combination disclosed in the Burgess application would have “poor knot strength properties.” (Ex. 6 at 2, 3). The ‘511 application eventually issued as the ‘446 patent.

VI. OPINIONS

- A. Invalidity based on 35 U.S.C. § 103 regardless of the construction of the term “PE” in the ‘446 patent

While I am not a legal expert, I have discussed the concept of obviousness with John Witherspoon, the legal expert retained in this case. I understand from the legal expert that in order for a patent claim to be valid it must satisfy the requirements for non-obviousness. Obviousness of a patent claim may be found by combining more than one prior art reference, or simply by combining a prior art reference with what was considered to be the state of the art as understood by a person of ordinary skill in the art at the time of the invention. In determining whether a patent claim is obvious, I understand that one must consider the level of skill in the art, the scope and content of the prior art, and the differences between the prior art and the invention in the patent claims.

I also understand that a prior art reference should be considered from the standpoint of what it teaches or suggests to one having the knowledge of a person of ordinary skill in the art at the time of the invention. I further understand that the prior art, or general state of the art, must provide to the person of ordinary skill in the art some suggestion or motivation to combine the teachings of the prior art references.

It is my opinion that a person of ordinary skill in the art, in February 1992, had an undergraduate degree in engineering or science and several years (e.g., approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications.

The '688 patent discloses a braided fabric prosthesis with the same structure as that listed in claims 1 and 8 of the '446 patent. The only difference between the '688 patent and claims 1 and 8 of the '446 patent are that the '688 patent describes a ligament prosthesis rather than a surgical suture. However, since the arts of braided ligament prosthetics and braided sutures are so similar and related, it is my opinion that a person of ordinary skill in the art, in February 1992, would have been motivated to apply the structure disclosed in the '688 patent to a braided surgical suture application.

The language of claim 1 of the '446 patent is listed in the left column of the chart below and the disclosure of the '688 patent is listed in the right column.

'446 Patent Claim 1	U.S. Patent No. 4,610,688
1. A surgical suture consisting essentially of	The '688 patent discloses a fabric prosthesis in the form of a ligament.
a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	<p>The '688 patent discloses a heterogeneous braid of a first set of fibers (set 9) and a second set of fibers (sets 11 and 13 when they are the same material). '688 patent at Table on col. 6, FIG. 2.</p> <p>The '688 patent discloses that the first and second sets of fibers are carrier braided. '688 patent at col. 8, ll. 63-64; col. 9, ll. 22-23. It was well-known in the art in</p>

	February 1992 that when carrier braiding was used there was direct intertwining contact made between the different sets of fibers.
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The '688 patent discloses that the first set of fibers (set 9) is polypropylene (PP). '688 patent at Table; col. 5, ll. 50-57.
b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and	The '688 patent discloses that the second set of fibers is one of PET (sets 11 and 13), nylon or aramid. '688 patent at col. 5, ll. 57-61. It further states that it is preferable to use the same second set of fibers for sets 11 and 13. '688 patent at col. 5, ll. 48-49.
c) optionally a core.	Although not required by claim 1 of the '446 patent, the '688 patent discloses a core. '688 patent at col. 1, ll. 62-64.

As I mentioned above, the '688 patent discloses all of the structure recited in claims 1 and 8 of the '446 patent except for the fact that the '688 patent is not directed to a surgical suture. However, it was well known in the art of biomedical fibers, in February 1992, that teachings of the suture field were often applied to teachings of the prosthetics field, and vice versa. For example, the '802 patent discloses novel polymeric

fibers with many biomedical applications, including sutures and prosthetics. In another example, *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* ("the DSM brochure") recommends UHMWPE for both suture and ligaments together. Ex. 7 at 4. In fact, prior to February 1992, it was common for the same researchers and designers to be working with both sutures and ligament prosthetics and to apply the teachings from one to the other. Therefore, it is my opinion that a person of ordinary skill in the art, in February 1992, knowing of the '688 patent, the '802 patent and the DSM brochure, would have been motivated to combine the teachings of the '688 patent and apply them to a suture application. Based on the state of the art at the time, there was good reason to believe that a braid construction that was successful for ligaments would also be successful for sutures.

The '802 patent also discloses the use of needles attached to suture, a fact well-known in the suture art at the time, and therefore, it is also my opinion that the combination of the '688 patent and the '802 patent and the general state of the art discloses all of the subject matter of claims 2 and 12 of the '446 patent.

B. Invalidity based on 35 U.S.C. § 102 or § 103 if the Court construes the term "PE" to include UHMWPE

I have reviewed DePuy Mitek's responses to Defendants' interrogatories and I understand that it is DePuy Mitek's opinion that the claim term "PE" includes UHMWPE. I disagree with this opinion, however, if the Court were to interpret the

claim term "PE" to include UHMWPE, there are several other prior art references that are related to the invalidity inquiry.

1. Invalidity based on § 102

I also understand that in order for a patent to be valid, it must claim subject matter that is new relative to the prior art. I understand that a patent claim is not directed to new subject matter if a single prior art reference discloses each limitation of the claimed invention. If the Court were to interpret "PE" to include UHMWPE, it is my opinion that the '575 patent discloses every limitation of the asserted claims. The reasons for my opinion are listed in the chart below which contains the language of claim 1 of the '446 patent in the left column and the disclosure of the '575 patent in the right column.

'446 Patent Claim 1	U.S. Patent No. 5,318,575
1. A surgical suture consisting essentially of	The '575 patent discloses a surgical suture. '575 patent at Title; col. 1, l. 7.
a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	<p>The '575 patent discloses that the fibers can be multifilament fibers that are braided. '575 patent at col. 3, ll. 49-51.</p> <p>The '575 patent also discloses a braid of one or more elongated filaments 26 of high molecular weight, high strength, where</p>

	<p>the remainder of the braid filaments 26 can be non-absorbable yarns. '575 patent at col. 4, ll. 8-24; FIG. 6.</p> <p>The '575 patent also discloses that the sutures are made on braiders having 12, 16, 24, 28 or 32 carriers. '575 patent at col. 7, ll. 59-61. When carrier braiders are used to construct a braid, there is direct intertwining contact made between the different braid filaments, a fact well-known in the braiding art.</p> <p>The '575 patent further discloses that first fibers are braided with second fibers to form an elongated member. '575 patent at claim 1.</p>
<p>a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and</p>	<p>The '575 patent discloses a suture having a braided construction comprised of one or more elongated filaments of the high molecular weight, high strength material, preferably, SPECTRA®. '575 patent at col. 4, ll. 9-12.</p> <p>The '575 patent also discloses that a suture having a braid construction may contain</p>

	SPECTRA® components. '575 patent at col. 7, ll. 59-60.
b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and	<p>The '575 patent discloses that the second fibers are nylon or PET. '575 Patent at column 3, lines 61-67; claims 11 and 12.</p> <p>The '575 patent also discloses that in addition to at least one elongated filament of ultra high molecular weight, high strength material, the remainder of the braid may be non-absorbable filaments. '575 patent at col. 4, ll. 9-23.</p>
c) optionally a core.	The '575 patent discloses a core, although one is not necessary for purposes of this claim. '575 Patent at claim 7.

Claim 8 has all the limitations of claim 1, but adds that the second fiber-forming material is PET. The '575 patent also discloses PET as a second fiber-forming material. Therefore, the '575 patent discloses every limitation of claim 8 of the '446 patent. Claim 2 has all the limitations of claim 1, and, in addition, adds that the suture is attached to a needle. Claim 12 likewise adds this needle limitation to claim 8. The '575 patent also discloses the use of a needle attached to a suture ('575 patent at col. 5, ll. 41-42). Therefore, it is my opinion that the '575 patent also contains every limitation of claims 2 and 12 of the '446 patent.

2. Invalidity based on 35 U.S.C. § 103 in view of the Burgess application and other prior art
 - a. The Burgess application combined with the Cohan article

The Burgess application describes a heterogeneous braid of UHMWPE and polyester and/or nylon for use as a fishing line. Thus, the Burgess application discloses every limitation of claim 1 of the '446 patent (if the Court interprets PE to include UHMWPE), except that Burgess is not a sterilized suture. As previously mentioned, the Burgess application was cited by the examiner in a rejection of claims 21-24 of the '511 application. In rejecting the claims, the examiner noted that the Burgess application disclosed a heterogeneous braided fishing line made up of two dissimilar polymers together to form a combined structure which embodies the desirable properties of each fiber. Ex. 4 at 4. The examiner reasoned that it would have been obvious to a person of ordinary skill in the art at the time to use a heterogeneous braid with these properties for a suture since: i) braided sutures were, at the time, well known in the art; ii) many of the requirements of sutures were comparable to those of fishing line – strength, low stretchability, etc.; and iii) many of the same materials were used to make both fishing lines and sutures. Ex. 4 at 5.

I agree with the examiner's reasoning that the Burgess application makes it known to braid two dissimilar fibers together to achieve the desired properties of each fiber, as well as the examiner's reasoning as to why it would have been obvious to a

person of ordinary skill in the art, in February 1992, to use a heterogeneous braid, such as that disclosed in the Burgess application, for a suture. In addition, in my opinion, one looking to find a manufacturer of a braided suture would seek out fishing line manufacturers as a potential braiding processor.

In response to the rejection, Ethicon's attorney did not dispute the examiner's finding that the Burgess application suggests the combination of two dissimilar fibers to achieve the desired properties of each. Rather, Ethicon stated that if one were to make a product with high tensile polythene (which in the Burgess application was UHMWPE), it would be "unsuitable for use as sutures" because UHMWPE has "low elongation" and because UHMWPE has "poor knot strength properties," including "poor knot strength and security." Ex. 6 at 2-3.

The Cohan article (published in 1985), however, teaches a person of ordinary skill in the art that Ethicon's attorney was incorrect on all counts. In fact, not only did Cohan teach a suitable suture, but he also taught that by using UHMWPE, one can build a superior suture. More specifically, the Cohan article explains that a superior suture can be made even though UHMWPE has low elongation and that the suture made of UHMPWPE had, among other things, *superior* knot strength (Ex. 8 at Table 2) and knot security, as compared with other more traditional suture materials at the time (e.g., nylon, polypropylene and polyester). Ex. 8 at 1. Thus, the Cohan article plainly suggests that UHMWPE has properties that can be used for a suture.

Taking these stark contradictions into account, it is my opinion, based upon my discussion with the legal expert, that if the patent examiner knew of the teachings of the Cohan article at the time Ethicon's attorney made those incorrect statements in distinguishing the '511 application, there would have been no reason for the patent examiner to change his original position.

The Cohan article also discloses the use of a needle attached to suture. Ex 8 at 1819. Therefore, it is my opinion that the Cohan article also contains every limitation of claims 2 and 12 of the '446 patent.

b. The Burgess application combined with the DSM brochure

The DSM brochure is another example of prior art that was known to persons of ordinary skill in the art in February 1992. The DSM brochure, dated 1987, recommends DYNEEMA brand UHMWPE for suture applications. Ex. 7 at 4. The same DSM brochure also explains that DYNEEMA is used for fishing line, a plain link between using that product in both fishing line and suture. It is my opinion that a person of ordinary skill in the art in February 1992, knowing of both the Burgess application (1989) and the DSM brochure (1987), would have been motivated to take the recommendation of the DSM brochure to use DYNEEMA in a suture application and to combine it in a braided suture with polyester and/or nylon, as in Burgess. It is also my opinion that the combination of the Burgess application and the DSM brochure, and

well-known principles in the suture art, discloses every limitation of claims 1 and 8 of the '446 patent.

Neither the Burgess article nor the DSM brochure specifically state that a braided suture may have a needle attached, however, it is my opinion that it was well known in the art of sutures, in February 1992, to attach a needle so that the suture can be used for its intended application. Therefore, it is also my opinion that the combination of the Burgess application and the DSM brochure, and well-known principles in the suture art, discloses every limitation of claims 2 and 12 of the '446 patent.

c. The Burgess application combined with the Harpell patents

In other examples, each of the Harpell patents, both from 1983, discloses the use of UHMWPE in suture applications. These are additional prior art references that were known to a person of ordinary skill in the art at the time of the invention in February 1992. It is my opinion that such a person would have understood from each of the Harpell patents that UHMWPE was a known suture material. It is also my opinion that since it was known at the time of the invention that fishing line and suture had similar requirements and used many of the same materials, that such a person would have been motivated to try and build a suture from a combination of UHMWPE and polyester and/or nylon in order to arrive at a superior suture. Therefore, it is my opinion that the combination of the Burgess application and either of the Harpell patents discloses every limitation of claims 1 and 8 of the '446 patent.

Neither the Burgess article nor the Harpell patents teach that a braided suture made with the combination of UHMWPE and polyester and/or nylon have a needle attached, however, it is my opinion that it was well known in the art of sutures, in February 1992, to attach a needle so that the suture can be used for its intended application. Therefore, it is also my opinion that the combination of the Burgess application and either of the Harpell patents, and well-known principles in the suture art, disclose every limitation of claims 2 and 12 of the '446 patent.

It is my opinion that any one of the above-described prior art references (i.e., the Cohan article, the DSM brochure and the Harpell patents), when combined with the Burgess application, would suggest to and motivate a person of ordinary skill in the art, in February 1992, to braid together UHMWPE and polyester and/or nylon for a suture application in order to arrive at a superior suture. For example, all the UHMWPE prior art disclose the advantages of UHMWPE for suture and the DSM brochure plainly links the suture art to the fishing line art. My opinion is further reinforced when I consider that a person of ordinary skill in the art is presumed to have known about all of these references at the same time in February 1992. The fact that several different people had suggested the use of, or actively used, UHMWPE in a suture is a strong suggestion to and motivation for one of ordinary skill in the art, in February 1992, to combine the UHMWPE teachings with the Burgess application to produce the claimed invention.

C. Invalidity based on 35 U.S.C. § 112

I have been informed by Mr. Witherspoon that in order for a patent to be valid, the specification must meet the “written description” requirement of 35 U.S.C. § 112, which means that it must reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. I further have been informed that in order for a patent to be valid, it must also satisfy the “enablement” requirement of section 112. That is, I have been informed that one must determine whether the specification, viewed from the perspective of a person skilled in the art, teaches such a person how to make and use the claimed invention without having to resort to undue experimentation.

It is my opinion that the ‘446 patent specification as filed in 1992 does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE. There is no disclosure at all within the ‘446 patent of using UHMWPE as a suture material. In February 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Consequently, the two materials are generally used for very different applications and one is not a substitute for the other. It has been my experience that, generally, when UHMWPE is intended to be included for a specified application, there is a special effort to make that fact known. For example, the ‘575 patent, the Burgess application, the Cohan article, Arthrex’s U.S. Patent No. 6,716,234, covering its FiberWire suture, Plaintiff’s patent application no. 2005/0149118, covering its Orthocord suture and

Linvatec's patent application no. 2004/0267313, covering its high-strength suture, just to name a few, all make clear that they are referring to UHMWPE. Such mention of UHMWPE is conspicuously absent from the '446 patent. Since UHMWPE is such a specialized material, and since there is no mention at all within the '446 patent of UHMWPE, it is my opinion that the '446 patent does not reasonably convey to a person of ordinary skill in the art at the time of the invention that the inventors were in possession of a sterilized surgical suture made at least in part with UHMWPE.

My opinion is further reinforced by what the '446 patent does disclose. For example, the '446 patent describes that the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The materials described as first fiber-forming materials are PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The materials described as second fiber-forming materials are PET, nylon and aramid.

The specification also states that the first fiber-forming materials are lubricious materials that act as lubricating yarns to improve the overall handling characteristics of the braid. The specification also explains that these lubricious materials are too weak to be used alone for most suture applications. The second fiber-forming materials are added to improve the overall strength of the braid. The '446 patent discloses that there is a tradeoff between the two fiber-forming materials – lubricious, but weak versus strong.

It is the very balance of lubricious yarns, which are good for handleability characteristics, with a strong yarn which is the hallmark of the patent specification. For example, the '446 patent relies heavily on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. But the point made by the inventors is that the gains in pliability and handleability by using the combination of lubricious, but weak materials with a stronger material outweighs the loss of suture strength resulting from combining a weaker lubricious material with the stronger material.

The '446 patent specification cautions against using more than about 80% of the lubricious yarns because such usage "may adversely affect the overall strength of the braid." This disclosure is also consistent with the tests described in the specification. For example, the Table depicts results for a multifilament braid made entirely (i.e., 100%) of a first fiber-forming material (i.e., CONTROL II made up of 100% PTFE). This braid was the weakest of the four braids tested, which is entirely consistent with the teachings of the specification.

These teachings of the '446 patent fairly describe the generally understood properties of general purpose PE – which is known to be lubricious, but weaker than the materials added for strength in the patent. Accordingly, the '446 patent specification would meet the "written description" requirement for general purpose PE. On the other hand, there is no written description of UHMWPE. Unlike general

purpose PE (or any of the other materials listed in the first fiber-forming group), UHMWPE is not a relatively weak material. Quite to the contrary, it is extremely strong and much stronger than any of the other materials identified in the first group of fiber-forming materials of claim 1. UHMWPE simply is not the kind of material which must be balanced against strong materials to achieve an acceptable suture. Moreover, for the reasons explained above, if the inventors had possession of UHMWPE as one of the first fiber-forming materials at the time of filing and believed that it met the teachings of the patent specification, I fully would have expected it to be specifically mentioned. The fact that it was not serves to reinforce my opinion that the inventors did not convey that they had possession of UHMWPE as a suture material at the time of the invention.

It is also my opinion that, viewed from the perspective of a person skilled in the art in February 1992, the '446 patent does not teach such a person how to make and use a surgical suture including UHMWPE without having to resort to undue experimentation.

As described above, nowhere does the '446 patent specification mention that UHMWPE can be used in the disclosed braided sutures. The entirety of the disclosure of the first fiber-forming materials is consistent with general purposes PE and inconsistent with UHMWPE. As described above, UHMWPE is a highly specialized material that also has very different properties as compared with every other material included in the '446 patent specification. The specification describes a manner of

braiding a first fiber-forming material with a second fiber-forming material, where the first fiber-forming material is lubricious and relatively weak and where the second fiber-forming material is added for strength. UHMWPE is known to be extremely strong and to have low elongation. These specialized properties must be taken into account when including UHMWPE in a braided structure as they will have an effect on the manufacturing processes.

For example, the fact that UHMWPE has such low elongation as compared with any of the other disclosed materials - and more importantly, as compared with the materials of the second fiber-forming materials - presents certain tensioning problems with the braiding operation that must be overcome. In addition, UHMWPE reacts differently to heat than any of the disclosed second fiber-forming materials, thus effecting the braids reaction to hot stretching. The '446 patent fails to advise whether this operation is even necessary when using UHMWPE. The '446 patent does not even mention UHMWPE, much less include any disclosure as to how a person of ordinary skill in the art, in February 1992, would go about addressing these specialized manufacturing concerns.

D. Failure to actually reduce invention to practice

I have reviewed DePuy Mitek's interrogatory responses and see that DePuy Mitek states the '446 patent was actually reduced to practice by February 2, 1989. Specifically, DePuy Mitek says that the inventors made "a PET/PTFE braid and PET/PP

braids that were carrier blended.” I understand from the legal expert that in order to establish actual reduction to practice, the inventor must prove that he constructed an embodiment that met all the limitations of the claim, and that he determined that the invention would work for its intended purpose.

Based on my review of Dr. Mark Steckel’s lab notebooks, and other Ethicon documents, it is my opinion that the inventors did not actually reduce the invention to practice in February 1989. Further, I have not seen any evidence that the inventors ever actually reduced the invention to practice prior to the filing date of the application for the ‘446 patent on February 19, 1992.

1. Inventors never actually reduced to practice a sterilized surgical suture

Among the limitations of each claim of the ‘446 patent is the requirement that the product be a “surgical suture” that is “sterilized.” There is no evidence that the inventors ever constructed a sterilized surgical suture. Rather, the evidence shows that the inventors constructed only a heterogeneous braid.

The heterogeneous braid constructed by the inventors is not a sterilized suture. Dr. Steckel testified that the heterogeneous braids were not sterilized, a limitation of the claims of the ‘446 patent. A product is not a suture until it is sterilized since it cannot be properly used without first being sterilized.

The patent examiner recognized the difference between a heterogeneous braid and a suture made from a heterogeneous braid. As the PTO examiner stated, a

heterogeneous braid is an intermediate product that is useful to make something other than the final product. That is, the heterogeneous braid the inventors did construct is not the claimed sterilized surgical suture, but rather, could be suitable for other applications. Examples of some other applications for which the heterogeneous braid may have been useful include fishing line (as the examiner mentioned), ligaments, ligatures, twine, tying materials, etc.

Further, the sterilization process can have a substantial effect on the braid properties. For example, many times, after sterilization, a braid can become more brittle, which can effect the braids performance in its intended application (e.g., a surgical suture). Since DePuy Mitek did not do this step, not only is it my opinion that they never reduced to practice a sterilized surgical suture, but it is also my opinion that they had no way of knowing whether a sterilized surgical suture made from the heterogeneous braids they constructed would have worked for its intended purpose.

2. Inventors never resolved technical problems with the invention


In addition, it is my opinion that the inventors never built any product that worked for its intended purpose because they encountered problems with core popping and braid looseness before the filing date of the '511 application and problems associated with braiding together two materials with dissimilar stress/strain properties that were never solved.

For example, the entry in Dr. Steckel's lab notebook dated February 2, 1989, states that "the carrier blend presented the most difficulties in core popping and braid looseness." Ex. 9. I have also reviewed an Ethicon document dated more than one year later which clearly indicates that there were still significant problems with constructing the invention. Specifically, I reviewed a handwritten note signed by B. Schwartz, dated February 7, 1990, which states that the invention "may offer significant advantages if technical problems of mixing 2 materials with dissimilar stress/strain properties can be overcome." Ex. 10. I understand from reading Dr. Steckel's deposition transcript that "B. Schwartz" was Barbara Schwartz, Dr. Steckel's manager at the time.

I have reviewed Dr. Steckel's deposition testimony in which he characterized the core popping and braid looseness problems as "a common braid defect." While that may be true in some instances, I do not see any evidence from the documents these were "common braid defects" that could easily be overcome or were overcome in these circumstances. In fact, Dr. Steckel testified that the core popping and braid looseness were caused by the problems associated with the stress/strain concerns presented by braiding two dissimilar products together by carrier blending. The inventors at the time had little experience with braiding dissimilar materials to construct a composite braid. It is my opinion that even as of February 1990, they did not yet fully understand how to overcome these, and possibly other, "technical problems." There is no evidence that these problems were solved before the filing date of the '511 application. I have not

seen evidence of continued work to solve these problems and I note that Ethicon never commercialized the invention.

In addition, while Dr. Steckel theorized at his deposition that the core popping and braid looseness problems were due to braiding tensions, there could be many other reasons for such problems. For example, Dr. Steckel testified that the braids were subjected to a hot stretching operation. Dissimilar materials may react differently when subjected to elevated temperatures. There is no evidence that the inventors even considered this as a possibility. Moreover, the fact that more than one year later, in February 1990, there were still "technical problems," tells me that there was a fundamental misunderstanding of what was causing these technical problems. If the core popping and braid looseness problems being experienced were simply routine, there would likely have been no reason to specifically note them on two separate occasions more than one year apart. Based on everything I reviewed, and also on my many years of personal experience with the manufacturing of braided sutures and fibers of different materials, it is my opinion that the inventors did not understand how to overcome the technical problems they were having with core popping, braid looseness, and braiding dissimilar materials together in 1989 and 1990. Since they never understood the nature of the technical problems and since there is no evidence that they ever resolved the technical problems, I do not believe they could have determined that the heterogeneous braid would work for its intended purpose as a sterilized surgical



suture. Therefore, I do not believe that the invention was ever actually reduced to practice before the February 19, 1992, filing date.

VII. CONCLUSION

The opinions expressed in this report are based on the information currently available to me. I specifically reserve the right to formulate and offer additional opinions based on any responsive reports received from DePuy Mitek, or on any additional information that may be provided to me, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, and additional evidence submitted by either party prior to or during trial.

Dated: March 3, 2006

Debi Prasad Mukherjee
Debi Prasad Mukherjee, Sc. D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent Nos. 5,314,446 was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 3rd day of March 2006:

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s/Salvatore P. Tamburo

EXHIBIT 6

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Expert Report of Dr. Matthew Hermes

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

treatment, stretching, annealing, coating, packaging design, sterilization, testing, assisting with obtaining 510(k) approval, and quality control.

2. In 1996, I authored the book "Enough for One Lifetime," the biography of Wallace Carothers, the inventor of Nylon. While writing this book from 1989-1996, I researched and studied the origins of synthetic fiber science including the history and development of nylon and polyester.

3. Before I worked at U.S. Surgical Corporation, I was a Research Director at Virginia Chemicals, at Celanese Co. from 1979-1983. Prior to being a Research Director, I was a Research Chemist, Supervisor, at E. I. DuPont from 1959-1979. At DuPont, I work with triaxial support systems and supervised a group that worked on elastomer coated fabrics.

4. From 1992-1994, I was an Adjunct Professor of Chemistry at the University of Wyoming. From 1995-1997, I was a Consultant at Colorado Advanced Technology Institute. In 2001 and 2006, I received two Small Business grants from the NIH for the development of unique all plastic manual wheelchairs and worked with Turbo Wheelchair company to develop, manufacture, and sell these unique devices.

B. Education

5. I have a Bachelor of Science in Chemistry from St. John's University, Brooklyn, NY, 1955. I have a Ph. D. in Chemistry from the University of Maryland, 1959. My mentor was Professor William Bailey who developed one of the earliest polymer science research groups in the country. My doctoral thesis related to polymers made using the Diels-Alder reaction. I also have a Masters of Arts in Liberal Studies from Wesleyan University, 1992.

6. A copy of my CV is attached under Ex. 1. A list of my publications and patents are set forth in my CV. In the past four years, I have not been deposed or testified as an expert witness.

7. I am being compensated at my customary hourly rate of \$200/hr. My compensation is not based on the outcome of the litigation.

II. Summary of Opinions

8. It is my opinion that claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 Patent ("the 446 Patent") (Ex. 2) are not invalid for obviousness over U.S. Patent No. 4,610,688 ("the 688 patent") when combined with U.S. Patent No. 5,120,802 ("the 802 patent"), the Dyneema SK60, High strength/high modulus fiber, Properties & Applications ("the DSM brochure")¹; and/or the general teachings of the art as defined by Dr. Mukherjee.²

9. It is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not anticipated by U.S. Patent No. 5,318,575³ ("the 575 patent") because the 575 patent does not teach, either expressly or inherently, all of the claimed limitations of these claims.

10. If the claims of the 446 Patent are construed to mean that "PE" includes UHMW PE, it is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not invalid for obviousness over U.K. patent application No. 2,218,312A to Burgess ("Burgess") and i) Cohan, et al., An Evolution of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture, Arch Ophtalmol – Vol. 103, December 1985 ("Cohan"); ii) the DSM brochure; and/or iii)

¹ I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that the DSM Brochure may not be prior art. For purposes of this report, I have been asked to assume that it qualifies as prior art.

² Dr. Mukherjee does not opine on the validity of claims 3-7 and 10-11 of the 446 over the references that he cites. I was not asked to consider the validity of claims 3-7 and 10-11 of the 446 patent over the references cited by Dr. Mukherjee.

³ I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that Chesterfield may not be prior art. For purposes of this report, I have been asked to assume that Chesterfield qualifies as prior art.

either one of U.S. Patent No. 4,563,392 or U.S. Patent No. 4,543,286 (“Harpell patents”).

11. If the claims of the 446 Patent are construed to mean that “PE” includes UHMW PE, it is my opinion that the claims of the 446 patent are not invalid for failing to satisfy the written description requirement because the 446 Patent specification describes the claimed invention sufficiently to convey to a person of skill in the art, that the inventors had possession of the sutures recited in the 446 patent claims, at the time the patent application for the 446 patent (February 1992) was filed with the U.S. Patent & Trademark Office.

12. If the claims of the 446 Patent are construed to mean that “PE” includes UHMW PE, it is my opinion that the claims of the 446 Patent are not invalid for failing to satisfy the enablement requirement because the claimed invention is sufficiently disclosed, such that a person of skill in the art, at the time the patent application for the 446 patent was filed with the U.S. Patent & Trademark Office (February 1992), could make and use the sutures claimed in the 446 Patent, without undue experimentation based on the 446 patent’s description of the claimed sutures.

13. It is my opinion that the inventors actually reduced to practice the inventions recited in claims 1, 8, and 9 of the 446 Patent at least as early as February 1989 and certainly at least as early as December 1989.

14. It is my opinion that, Mr. Goodwin’s and Dr. Steckel’s statements, that Mr. Witherspoon said were materially inconsistent were not inconsistent, much less materially inconsistent.

15. I may testify about certain suture properties and suture testing.

III. Legal Framework for My Opinions

16. The patent laws form the legal framework for my opinions. My understanding of the U.S. Patent Laws is as follows. I understand that the patent statute states that patents are presumed valid. 35 U.S.C. §282. I further understand that each patent claim is presumed valid, and therefore an invalidity analysis must be done on a claim-by-claim basis. I understand that because of this presumption, Arthrex or Pearsalls must put forth “clear and convincing” evidence of invalidity to overcome this presumption of validity. It is my understanding that this a higher burden of proof than a preponderance of the evidence standard, but less than a reasonable doubt standard.

A. The Law of Anticipation

17. It is my understanding that a patent claim is invalid if it is not novel (which I understand is referred to as being “anticipated”), if a single prior art reference teaches, expressly or inherently (necessarily present), all of the claim limitations arranged in the same manner as the claim and enables one of ordinary skill in the art to make and use the invention. I understand that the test for lack of novelty is generally a two-part test. First, the meaning and scope of the claims are determined by the Court. Second, once the claim scope has been determined or construed, the next step in assessing a patent claim’s validity is deciding whether one piece of prior art describes all of the claim limitations arranged as claimed. Because the Court has not yet construed the claims of U.S. Patent No. 5,134,446, I have been asked to assume a certain claim construction.

B. The Law of Obviousness

18. I also understand that a claim is invalid due to obviousness under 35 U.S.C. §103 if there is clear and convincing evidence showing that the differences between the claim and the prior art are such that the claimed subject matter as a whole would have

been obvious to a person having ordinary skill in the art at the time the invention was made.

19. I understand that determining obviousness involves the following four factual inquiries: 1) the scope and content of the relevant prior art; 2) the level of ordinary skill in the art; 3) the differences between the claimed invention and the prior art; and 4) secondary considerations of non-obviousness.

20. I understand that the “scope and content of the relevant prior art” includes all art that is reasonably pertinent to the particular problem with which the invention was involved. In other words, the relevant art is defined by the nature of the problem confronting the would-be inventor. The relevant prior art encompasses art in the inventor’s field of endeavor and any analogous art.

21. I understand that “analogous prior art” is art that, although not within the inventor’s field of endeavor, is still reasonably pertinent to the particular problem to be solved. I understand that a reference is “reasonably pertinent” if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering the problem.

22. In the case where obviousness is based on the combination of prior art references, I understand that there must be a reason, suggestion, or motivation in the prior art or elsewhere, that would have led a person of ordinary skill in the art to combine the prior art references to arrive at the claimed invention. The relevant inquiry is whether a skilled artisan, confronted with the same problems as the inventor, and with no knowledge of the claimed invention, would select the elements from the prior art for

combination in the manner claimed. In selecting prior art references relevant to the obviousness inquiry, it is considered improper “hindsight” to define the problem to be solved in terms of its solution (*i.e.*, the claimed invention).

23. I also understand that it is not enough to find every element of a claimed invention in the prior art. There must be a reason, suggestion, or motivation to combine the prior art in such a way so as to arrive at the claimed invention.

24. I understand that so-called “secondary considerations of non-obviousness,” when present, must also be considered as part of the obviousness determination. I understand that these are objective evidence of non-obviousness, and include, among other things, evidence of commercial success, copying, long-felt but unresolved need, failure of others, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, skepticism of persons skilled in the art before the invention, and tribute by others. These secondary considerations provide objective evidence of how the patented device is viewed in the marketplace by those directly interested in the product.

C. The Law of Written Description & Enablement

25. I understand that another condition of validity is that a patent must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, *i.e.*, that the patentee invented what is claimed.

26. I understand that another condition of validity is that a patent must describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the invention without undue experimentation. I understand that routine details do not need to be disclosed in a patent because they are readily

apparent to one of ordinary skill in the art and that patent specifications need not be as detailed as production specifications.

D. Actual Reduction to Practice

27. I understand that invention requires a conception and reduction to practice. I understand that conception is the formulation of an idea in one's mind of a definite and permanent idea. I further understand that actual reduction to practice typically occurs when the claimed invention is constructed and evaluated sufficiently to know that it will work for its intended purpose.

IV. Claim Construction

28. As mentioned above, I understand that the first step in an invalidity analysis is to determine the meaning of the claims. I understand that the Court will determine the meaning of the claim terms in the 446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

“PE” – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

“Consisting essentially of” – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

“Direct intertwining contact” means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

“Volume fraction of the first set of yarns in the braided sheath and core” means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions.

V. Materials Considered in Forming My Opinions

29. In forming my opinions, I have considered the 446 Patent, its file history, and the reports of Dr. Debi Prasad Mukherjee and John F. Witherspoon, and Peter Dreyfuss’s, Brian Hallet’s, and Dr. Mark Steckel’s, and Mr. Donald Grafton’s deposition testimony.

A list of the documents that I used in forming my opinions is set forth in Ex. 16.

VI. Claims 1, 2, 8, 9, & 12 of the 446 Patent Are Not Invalid Over the References Discussed by Dr. Mukherjee

A. The Level Of Ordinary Skill In The Art

30. I understand that Dr. Mukherjee has opined that a person of ordinary skill in the art, “in February 1992, had an undergraduate degree in engineering or science and several years (e.g., approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications.”

(Mukherjee at 10). I disagree because this definition of ordinary skill is too broad. It encompasses persons who do not have any relevant technical degrees and relevant experience. For example, Dr. Mukherjee’s definition includes someone with no education that is relevant to suture design and no suture design experience.

31. In my opinion, between 1988-1992, a person of *ordinary* skill in the art would likely be a scientist in chemistry or a chemical, mechanical, or biomedical, biomechanical, or textile engineer (or other similar technical field) practicing in the field of suture design or development and having about 2 to 3 years of experience in the suture design field or person without such a degree but having about eight years experience in suture design or development. In my opinion, between 1988-1992, a person of skill in the art would likely be a scientist in chemistry or a chemical, mechanical, or biomedical, biomechanical, or textile engineer (or other similar technical field) practicing in the field of suture design or development and having about 1 to 2 years of experience in the suture design field or person without such a degree but having about five years experience in suture design or development.

32. Both the person of ordinary skill in the art and the person of skill in the art would have known that a broad spectrum of sutures were available for surgical use between 1988-1992. During that period of time, commercial sutures generally were classified as either monofilaments or multifilaments.

33. Both the person of ordinary skill in the art and the person of skill in the art would also have known that sutures are designed based on a balance of several properties including, among others, knot strength, knot security, pliability, tissue drag, run down, absorbability, and biocompatibility. Also, one of ordinary skill in the art would have understood that generally monofilaments and multifilaments possessed different properties giving them advantages and disadvantages over each other. For example, generally, monofilaments had less tissue drag, but would lack relative pliability and knot security, when compared to multifilaments. Whereas, multifilaments, generally, would

be more pliable and have greater knot security, but relative poor knot run down and tissue drag, when compared to monofilaments.

B. Claim 1 of the 446 Patent Is Not Invalid For Obviousness Over The 688 Patent When Combined With The 802 Patent, the DSM Brochure, And/Or The General Teachings Of The Art As Defined By Dr. Mukherjee

34. I understand that Dr. Mukherjee has opined that claims 1, 2, 8, and 12 of the 446 Patent are invalid as obvious over the 688 patent when combined with the 802 patent, the DSM Brochure and/or the general teachings of the art as defined by Dr. Mukherjee (Mukherjee at 3, 13). I disagree with Dr. Mukherjee's opinions for the reasons set forth below.

1. The Scope And Content Of The 688 Patent, The 802 Patent, & The DSM Brochure

35. Below I discuss the scope and content of the 688 patent, the 802 patent, and the DSM brochure as they would have been understood by a person of ordinary skill in the art between 1988 and 1992.

a) The Scope & Content of the 688 Patent

36. The 688 patent teaches a ligament prosthesis, not a suture (Ex. 3 at 2:14). Dr. Mukherjee agrees (Mukherjee at 11). According to the 688 patent, the disclosed ligament prosthesis is designed to have a "yield strength in tension and a longitudinal elasticity that are at least as comparable to that of a human ligament and a resistance of longitudinal elastic deformation in tension that approximates that of a human ligament" (Ex. 3 at 2:16-19). The 688 patent teaches a tubular triaxial-fabric braided element (Ex. 3 at 3:49-50) having three sets of fibers, designated 9, 11, and 13 (Ex. 3 at 3:65-66). Fibers 9 are straight, and fibers 11 and 13 are helically disposed in the wall of the tubular fabric prosthesis (Ex. 3 at 3:66-4:3). The 688 patent teaches that the straight

fibers 9 are made from a group of materials one of which is hard elastic polypropylene (Ex. 3 at 5:50-57). Fibers 11 and 13 are made from a different group of materials, but are taught to be the same in a given prosthesis (Ex. 3 at 5:57-6:2; Table of Fibers). The triaxial braid taught by the 688 patent is manufactured on a triaxial braiding machine (Ex. 3 at 4:14-36).

b) The Scope & Content of the 802 Patent

37. The 802 patent describes that the potential biological or medical uses of block copolymers having carbonates as their major component had not been appreciated (Ex. 4 at 1:35-36). Accordingly, the 802 patent teaches a polycarbonate-based, block copolymer having at least one flexible block and at least one block, which is more crystalline than the first flexible block (Ex. 4 at 1:6-9). The 802 patent provides examples of the two blocks, which it refers to as “A” and “B” blocks (Ex. 4 at 2:47-3:60). It provides a more detailed description of specific block copolymers throughout the patent (Ex. 4 at 4:8-44; 4:48-12:30). The main focus of the 802 patent to one of ordinary skill in the art between 1988 and 1992 is specific block-copolymer structures that may have useful applications.

38. According to the 802 patent, the block copolymers that it teaches are “particularly suited to be spun into fibers, extruded into films, tubings, and devices of many shapes and sizes” (Ex. 4 at 1:9-12; see also 12:55-65). The 802 patent describes many general applications for the block polymer including forming fibers or yarns that may be “woven, braided and/or knitted into fabrics having various structural configurations” (Ex. 4 at 15:41-42). Also, the 802 patent states that the block copolymers can be formed into fibers that are “preferably used as sutures or fasteners” (Ex. 4 at 15:44-45). The 802 patents states that the block copolymers that are “particularly useful are woven or

knitted fabrics in the form of tubular prostheses of varying shapes, lengths, and diameters” and illustrative of these tubular prosthesis are “vascular grafts, nerve guidance channels, and the like” (Ex. 4 at 15:60-62).

c) The Scope & Content of the DSM Brochure

39. DSM is a company that manufactures fibers for use in different applications. The DSM brochure advertises that Dyneema SK60 can be used for many different applications, including, cable, bow strings, ropes, strings, sutures, ligaments and long line and sport sea fishing (Ex. 5 at PR08424). The DSM brochure describes that polyethylene properties cover the range from 1 N/tex specific strength and 25 N/tex specific modulus to 3.5 N/tex specific strength and 150 N/tex specific modulus (Ex. 5 at PR08422). It also notes that Dyneema SK60 falls within this range at 2.7 N/tex and 90 N/tex (Ex. 5 at PR08422). Accordingly to the brochure, the Dyneema SK60 was a new material, and it further notes the knot strength of certain SK60 fibers, not braids (Ex. 5 at PR08426). The brochure does not mention knot security, provide any analysis regarding the knot security of Dyneema SK60N, or provide any specific analysis of properties associated with braids (Ex. 5).

40. There is no discussion in the Dyneema brochure of a heterogeneous braid. There is no discussion in the DSM Brochure of using PET, Nylon, or aramid in combination with UHMW PE fibers. Further, there is no description of how to construct braids or using Dyneema fibers to make braided sutures.

41. I note that the DSM brochure provided with Dr. Mukherjee’s report (Ex. 7 of Mukherjee report) is not completely readable. For example, the knot strengths of the fibers are not readable. Thus, I am not able to comment on the teachings of the DSM

brochure as a whole. I understand, however, that a reference is supposed to be considered as a whole based on all of its teachings.

2. The Differences Between The 688 Patent, the 802 Patent, the DSM Brochure, And Claim 1 of the 446 Patent

42. Claim 1 of the 446 Patent claims a *suture* (Ex. 2 at 8:62-10:19). The 688 patent does not teach a suture.

43. Claim 1 of the 446 Patent claims certain yarns that are braided in “direct intertwining contact” (Ex. 2 at 8:67). The 688 patent also lacks a yarn from the claimed first set of fiber-forming materials yarns braided in “direct intertwining contact” with a yarn from the claimed second set of fiber-forming materials.

44. Dr. Mukherjee has opined that (i) the first-fiber forming material of claim 1 of the 446 Patent is fiber set 9 in the 688 patent; (ii) the claimed second-fiber forming material of claim 1 of the 446 patent is either fiber set 11 or 13 in the 688 patent; and (iii) the claimed direct intertwining contact of claim 1 of the 446 patent is the braiding of fiber set 9 with either fiber set 11 or 13 in the 688 patent (Mukherjee at 11-12). I disagree. Element 9 in the 688 patent is a straight fiber, while the elements 11 and 13 are helically wound around element 9 (Ex. 3 at Fig. 1 & 2; 3:65-4:14). Thus, element 9 is not mechanically interlocked with either element 11 or 13 and is not braided with either element 11 nor 13 “in direct intertwining contact,” as claimed in the 446 Patent. For example, in a direct intertwining braided construction, one set of yarns is interlocked with the other, so that they are held within the braid by the other set of yarns (see Ex. 2 at 5:18-26). In contrast, in the 688 patent, fibers 9 are not interlocked with fibers 11 or 13.

45. There are also differences between claim 1 of the 446 patent and the 802 patent. Claim 1 of the 446 Patent recites a *heterogeneous braid* of two yarns, a *direct intertwining contact* braid of braided yarns, and *specific yarns* in the braid (Ex. 2 at 8:63-9:10). Although the 802 patent discloses a suture of certain copolymers, the 802 patent does *not* recite a heterogeneous braid of two yarns, a direct intertwining contact braid of yarns, nor the specific yarns claimed in the 446 patent in a braid. Rather, the 802 focuses on a new block copolymer structure and mentions general applications for it. There is no mention of braiding the claimed materials as braided in claim 1 of the 446 patent. Thus, although the 802 patent refers to a suture, it is missing most of the other claim elements.

46. Similarly, there are also differences between the invention of claim 1 of the 446 Patent and the DSM Brochure. Claim 1 of the 446 patent claims a heterogeneous braid (Ex. 2 at 8:63-9:10). The DSM brochure does not disclose or suggest a heterogeneous braid.

47. The 446 Patent claims a heterogeneous braid of PE with nylon, aramid, or PET (Ex. 2 at 8:63-10:19). The DSM brochure does not disclose or suggest using nylon, aramid, or PET with Dyneema at all, let alone in a suture, or in a heterogeneous braided suture wherein dissimilar yarns are in direct intertwining contact.

3. One of Ordinary Skill in the Art Would Not Have Been Motivated To Combine The 688 Patent And The 802 Patent At The Time Of The Invention To Form The Suture Of Claim 1 Of The 446 Patent

48. Dr. Mukherjee opines that one of skill in the art would have been motivated to combine the 688 and 802 patents in such a way so as to form the claimed invention (Mukherjee at 13). I disagree because there are significant differences between the 688

and 802 patents and the invention of claim 1 of the 446 patent. Further, there is no suggestion or teaching to modify them or combine them in such a way, so as to form the suture of claim 1 of the 446 patent.

49. There is no motivation to modify either the 802 or 688 patents in light of the teachings of the other to form the claimed invention.

50. One of ordinary skill in the art would not have not have been motivated to modify the 688 patent in light of the 802 patent to form the claimed invention because there are significant differences between the suture of claim 1 of the 446 patent and the 688 and 802 patents. Neither the 688 patent nor the 802 patent teaches a suture having a heterogeneous braid in direct intertwining contact. Further, neither teaches the materials claimed in the 446 patent braided in direct intertwining contact. Given these significant differences, one of ordinary skill in the art would not have been motivated to form the claimed invention from the 688 and 802 patents.

51. Dr. Mukherjee has opined that merely because the 802 patent discloses a block copolymer that can be used as a suture or in a ligament prosthesis, one of ordinary skill in the art would have been motivated to modify the tubular prosthesis of the 688 patent into the invention of claim 1 of the 446 patent. But the triaxial-braided fabric element of the 688 patent is braided on a triaxial braider. One of ordinary skill in the art at the time of the invention would not have been motivated to form a suture, as recited in claim 1 of the 446 Patent, based on the teachings of the 688 patent, because the claimed suture could not be made with a triaxial braider. Notably, a triaxial braider is generally used for larger woven tubular structures, not sutures. For example, the 688 patent examples 1 and 2 are hollow-tubular prostheses that have a circumference of about 21 and 19 mm

(Ex. 3 at 8:58-9:17). In contrast, sutures generally have a diameter on the order of less than 2 mm in diameter (See Ex. 11 at sec. 24) (a #2 suture is about 0.55 mm. in diameter). The structure taught by the 688 patent is simply too big for use as a suture.

52. I also disagree with Dr. Mukherjee's suggestion that the ligament prosthesis taught by the 688 patent could just be used as a suture. The structure taught by the 688 patent would have to be significantly modified to be a suture. Dr. Mukherjee provides no explanation of how one of ordinary skill in the art would have been motivated to change the triaxial-braided fabric disclosed in the 688 patent into a suture. Also, he provides no explanation of how the teachings of the 688 patent can be applied to the braiding equipment that is used for sutures to form a braid as claimed. Nor does the 802 patent provide any such explanation.

53. I further disagree with Dr. Mukherjee's opinion that just because the 802 patent references sutures and prosthesis, it provides motivation to change the ligament prosthesis of the 688 patent in such a way so as to form the suture of claim 1 of the 446 patent. The 688 patent teaches a ligament prosthesis that should be designed to have elastic behavior that matches the physical properties of the ligament being repaired (Ex. 3 at Fig. 5; 7:29-33). One of ordinary skill in the art at the time of the invention would have known that sutures generally are designed not to have elastic behavior that matches a ligament's physical properties. Sutures have a different function than the ligament disclosed in the 688 patent. Generally, sutures hold tissue together during the healing process. Therefore, sutures are typically designed to have some elasticity, but less elasticity than the ligament prosthesis taught by the 688 patent. Thus, between 1998-1992, one of ordinary skill in the art reading the 688 and 802 patents would have

recognized the differences between the tubular ligament prosthesis of the 688 patent and a suture, and would not have been motivated to modify the ligament prosthesis of the 688 patent into a suture, let alone into the suture recited in claim 1 of the 446 patent.

54. Dr. Mukherjee appears to say that there is motivation to combine the 688 and 802 patents because “the arts of the braided ligament prosthetics and braided sutures are so similar” (Mukherjee at 11) and because “teachings of the suture field were often applied to teachings of the prosthetics field, and vice versa” (Mukherjee at 12). In this instance, I disagree because the properties of the ligament prosthesis taught by the 688 patent and a suture are much different as described above. Further, the 688 ligament prosthesis is not suitable for use as a suture. Moreover, Dr. Mukherjee has not pointed to any motivation to combine the references in such a way so as to form the claimed invention. The mere fact that the 802 patent refers to both sutures and ligaments does not provide motivation to modify the 688 patent teachings in such a way, so as to form the suture of claim 1 of the 446 patent.

4. One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine the 688 Patent with the DSM Brochure To Form The Suture of Claim 1 of the 446 Patent

55. Dr. Mukherjee has opined that one of ordinary skill in the art would have been motivated to combine the 688 patent and the DSM Brochure in such a way so as to form the claimed invention. I disagree because there are significant differences between the 688 patent and the DSM brochure and the suture of claim 1 of the 446 patent, and there is no suggestion or teaching in them to combine them in such a way so as to form the suture of claim 1 of the 446 patent.

56. There was no explicit motivation in either the 688 patent or the DSM brochure to modify either in light of the teachings of the other to form the claimed invention.

57. As explained above with reference to the combination of the 688 and 802 patents, there are significant differences between the 688 patent and claim 1 of the 446 patent. The 688 patent does not describe a suture. Nor does the 688 patent describe the claimed yarns of the 446 patent in direct intertwining contact. Also, the DSM brochure fails to describe any braiding operations, braiding constructions for a suture, heterogeneous braids, or the material claimed in the 446 patent. Thus, the DSM brochure does not cure the deficiencies in the teachings of the 688 patent. Because of the significant differences and a lack of any explanation in the 688 patent or the DSM brochure as to how to overcome these differences, there is no motivation to combine or modify them in such a way so as to form the suture of claim 1.

58. As described above, the ligament prosthesis taught by the 688 patent would have to be significantly modified in order to be formed into a suture, much less the suture of claim 1 of the 446 patent. The DSM brochure does not describe how to modify the triaxial braided ligament prosthesis of the 688 patent into a suture, much less the suture of claim 1 of the 446 patent. Therefore, for similar reasons as described above with reference to the 802 patent, there is no motivation to modify the ligament prosthesis of the 688 patent into suture.

59. Dr. Mukherjee cites to the DSM brochure for the mere proposition that it “recommends UHMWPE for both suture and ligaments together” (Mukherjee at 13). But this citation say nothing about how to modify the tubular prosthesis taught by the 688 patent to form the suture of claim 1 of the 446 patent. Thus, one of ordinary skill at the

time having the 688 patent and the DSM brochure would not have been motivated to modify the tubular prosthesis taught by the 688 into the suture claimed in the 446 patent.

5. One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine the 688 Patent with the General State of the Art At The Time Of The Invention To Form The Suture of Claim 1 of the 446 Patent

60. Dr. Mukherjee also opines that the 446 Patent claims are obvious over the 688 patent when combined with the “general state of the art” (Mukherjee at 13). He appears to state that the general state of the art is that “teachings of the suture field were often applied to teachings of the prosthetics field, and vice versa” (Mukherjee at 12). But this does not provide motivation to modify the ligament prosthesis taught by the 688 patent to form the claimed suture because it does not describe how to (i) modify the triaxial tubular prosthesis of the 688 patent to form a suture; (ii) how to make a suture having the same structure as the triaxial tubular prosthesis of the 688 patent; or (iii) how to modify the triaxial tubular prosthesis of the 688 patent to have the limitations of the suture of claim 1 of the 446 Patent, including direct intertwining contact between the first and second fiber-forming materials.

6. Secondary Considerations of Non-obviousness

61. I also understand that commercial success of the claimed invention is indicative of the non-obviousness of the suture claimed in the 446 patent. I assume that the FiberWire products are covered by claims 1, 8, 9, and/or 12 of the 446 patent.

62. I have reviewed portions of Dr. Gering's report on damages.⁴ The report shows the large number of sales of FiberWire products, and less sales of TevDek products (Gering Rpt. at 10-11). I understand that Tevdek is a braided polyester suture (Ex. 12 at 36:17-18; 36:25-37:1). Dr. Gering's report also shows that the FiberWire suture drove the sale of Arthrex's suture anchor products because the same Arthrex anchor was sold with FiberWire and Tevdek suture and the FiberWire products outsold the Tevdek products (Gering Rpt. at 7-13).

63. I also note that Mr. Grafton described Arthrex's Tevdek suture as not acceptable (Ex. 12 at 45-46), thereby indicating that the attributes of FiberWire relative to Tevdek have been a reason for the sales of its FiberWire products. For example, Mr. Grafton testified that Arthrex was having "issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon" (Ex. 12 at 44:13-16). He further explained that surgeons, who were friendly to Arthrex, had broken Tevdek sutures when trying to tie knots (Ex. 12 at 44:18-45:9). According to Mr. Grafton, the solution to this commercial problem was braiding UHMW PE with PET in direct intertwining contact (Ex. 12 at 44:5-54:5). Thus, Mr. Grafton's experience with TevDek and FiberWire confirms that FiberWire has been successful due to its braid construction which is claimed in the 446 patent.

64. I have also reviewed ¶¶ 73-77 of Dr. Brookstein's report. In his report, he describes that FiberWire's benefits that are marketed by Arthrex are due to the features claimed in the 446 patent. Based on Dr. Brookstein's report, Mr. Grafton's testimony, and Dr. Gering's report, FiberWire's commercial success can be attributed to the suture

⁴ I assume that Dr. Gering's and Dr. Brookstein's reports are true. I am not opining on the issues for which they are opining.

claimed in the 446 patent. Thus, FiberWire's commercial success reflects the non-obviousness of at least claims 1, 2, 8, 9, and 12 of the sutures claimed in the 446 patent.

65. I also understand that praise by others is indicative of non-obviousness. I understand that Mr. Grafton had tried making a braided suture with a braid having just UHMW PE, but failed because the UHMW PE was too lubricious (Ex. 12 at 53-54). After he was unsuccessful with making a suture from just UHMW PE, Mr. Grafton thought of the idea of braiding UHMW PE yarns with PET yarns in direct intertwining contact (Ex. 12 at 53). When he explained his idea to Dr. Burkhart, who I understand is a surgeon, Dr. Burkhart described the idea as "killer" (Ex. 12 at 54). But Mr. Grafton's idea was patented in claims 1, 2 and 8 of the 446 patent. Thus, Dr Burkhart's praise for the idea was really a recognition of the importance of the 446 patent and indicative of the non-obviousness of at least claims 1, 2, and 8 of the 446 patent.

7. Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over the 688 Patent In Light Of The References Cited by Dr. Mukherjee

66. Based on (i) the scope and teachings of the 688 patent, the 802 patent, the DSM brochure, and the general state of the art referred to by Dr. Mukherjee; (ii) the differences between claim 1 of the 446 patent and the art cited by Dr. Mukherjee; (iii) the level of ordinary skill in the art; and (iv) the secondary considerations of non-obviousness, claim 1 of the 446 patent is non-obvious.

67. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 "is attached to a needle" (Ex. 2 at 9:11-12). Because claims 2 and 12 contain all of the limitations of claim 1 plus an additional limitation, they are non-obvious for the same reasons as claim 1.

68. Claim 8 of the 446 patent recites that the “second set of yarns is PET” (Ex. 2 at 10:7-8), but is otherwise the same as claim 1. In order to show the obviousness of claim 8, the references must suggest (or motivate one of ordinary skill in the art to form) a suture having all of the limitations of claim 1 and the claimed second yarn being PET, as opposed to Nylon, PET, or aramid as recited in claim 1. The art relied upon by Dr. Mukherjee does not disclose the claimed second yarn as being PET for the reasons set forth above with respect to claim 1. Accordingly, except for my opinions regarding Nylon and aramid, my opinions described above with reference to the 688 patent and the other references apply to claim 8.

69. Claim 9 of the 446 patent is also non-obvious for the same reasons as claims 1 and for additional reasons. Claim 9 of the 446 patent recites that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent” (Ex. 2 at 10:9-11; 18-19). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is non-obvious for this additional reason.

C. Claims 1, 2, 8, 9, and 12 of The 446 Patent Are Not Anticipated By Chesterfield

70. Dr. Mukherjee opined that Chesterfield “discloses every limitation of the asserted claims” (Mukherjee at 14). I disagree. The 575 patent does not disclose many limitations of claims 1, 2, 8, 9, and 12 of the 446 Patent.

71. The 575 patent does not disclose to one of ordinary skill in the art a heterogeneous braid of the claimed yarns from the first-fiber forming materials with the second fiber-forming materials in direct intertwining contact. Further, the 575 patent does not teach a suture having a braid of PE (including UHMW PE) with PET, Nylon, or

aramid. I understand that in order for the 575 patent to anticipate the 446 patent claims, it must disclose every limitation of the 446 Patent claims (expressly or inherently) arranged in the same way as claimed in the 446 Patent claims. Because the 575 patent does not teach all of the limitations of the claimed invention arranged in the same way, it is my opinion that there is no anticipation.

72. In general, I disagree with Dr. Mukherjee because he picks and chooses different teachings of the 575 patent and combines them in a way that is not described in the 575 patent and then concludes that the 575 patent teaches the claimed invention. Basically, he forms the claimed invention by selecting teachings about a sternum closure device in the 575 patent and combining them with select teachings about a suture repair device in the 575 patent. But I disagree with his analysis because the 575 patent does not expressly or inherently describe the claimed invention. I address some of Dr. Mukherjee's specific points below.

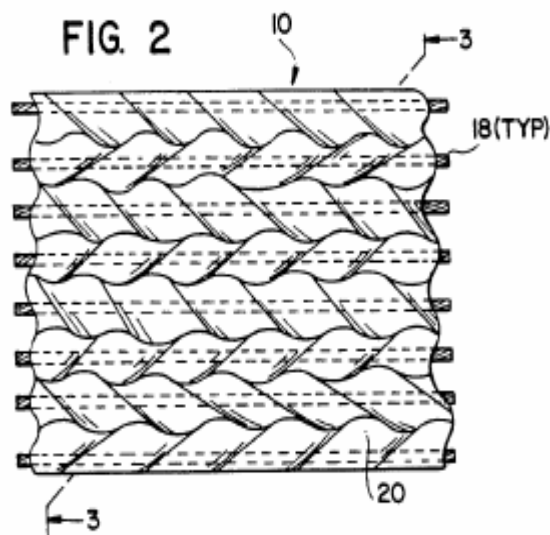
73. Dr. Mukherjee cites to column 3, lines 61-67, of Chesterfield as disclosing nylon or PET. I disagree. This citation does not refer to nylon or PET. In fact, column 3, lines 61-67, specifies that the material 20 is a "bioabsorbable polymeric material such as . . . polyester" (Ex. 6 at 3:63-67). Neither nylon nor PET are bioabsorbable polyesters; they are non-absorbable materials. Thus, column 3, lines 61-67 is not a disclosure of either PET or nylon.

74. Dr. Mukherjee also cites to column, 3, lines 61-67, of Chesterfield as disclosing nylon or PET braided with UHMW PE in a *suture*. But I disagree. The 575 patent at column, 3, lines 61-67, describes that fibers 20 are used in the outer structure in the *sternum closure ribbon 10*, not a suture. Thus, this citation to col. 3, lines 61-67 does

not teach nylon or PET braided in a suture, much less braided in direct intertwining contact with UHMW PE.

75. Dr. Mukherjee cites the filler yarns 20 of the *sternum closure device* as being braided with the UHMW PE in the *spiroid braid* of Fig. 7. But the filler yarns 20 are from a *sternum closure device* (Figs. 2 and 4) and the UHMW PE (to which he cites) is from a *spiroid braid* (Fig. 7). Thus, they are not braided in direct intertwining contact as required by the 446 patent claims.

76. Further, Chesterfield does not teach a heterogeneous braid for the braided fibers 20 in the sternum closure device 10 (below). Rather, Chesterfield teaches that the braided fibers 20 are in a homogeneous woven structure (Ex. 6 at 3:61-4:1, 4:39-47).



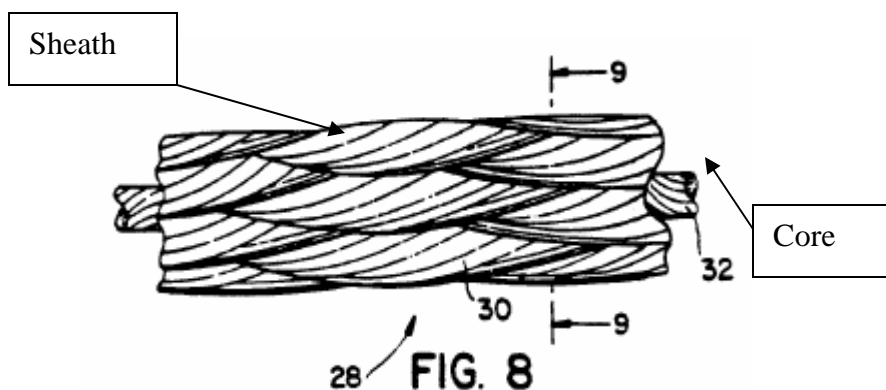
Therefore, his citation to Chesterfield's sternum closure device does not disclose nylon, aramid, or PET braided in direct intertwining contact with PE in a suture, as claimed in the 446 Patent.

77. Again, Dr. Mukherjee piecemeals two materials from two different structures to describe the heterogeneous braided suture as claimed in the 446 Patent. Specifically,

Dr. Mukherjee takes the UHMW PE from the core of the *hollow braid* of Figs. 8 and 9 and matches it with either the (1) bioabsorbable polyester of the *sternum closure device* or (2) the material of the *spiroid braid* of Fig. 7. This picking and choosing of two different materials from two different structures does not teach a single suture construction having the claimed first and second fiber forming materials braided in direct intertwining contact as claimed in the 446 Patent.

78. Dr. Mukherjee also cites to column 7, lines 59-60, as disclosing a heterogeneous braid with direct intertwining contact where one of the yarns is PE (Mukherjee at 14-16). But column 7, lines 59-60 of Chesterfield only describes PE in the core. The PE referred to in column 7, lines 59-60, is not in the sheath, is not described as braided with another material, is not described as braided with the claimed second fiber-forming materials (nylon, aramid, or PET), and is not described as braided in direct intertwining contact with the claimed second fiber-forming materials.

79. Dr. Mukherjee also cites to claims 11 and 12 of the 575 patent as disclosing nylon and polyester respectively braided in direct intertwining contact with UHMW PE in a heterogeneous suture braid as claimed in the 446 patent. I disagree. Claims 11 and 12 of the 575 patent refer to second non-absorbable fibers as being formed from either nylon or polyester. But claims 11 and 12 of Chesterfield do not specify how the second fibers are braided with the claimed first fibers. For example, Chesterfield claims 11 and 12 do not recite that the first and second fibers are braided in direct intertwining contact, as opposed to a core-sheath arrangement (like that described in Chesterfield Figs. 8, reproduced below, & 9), with the first fiber materials only in the core and the second fiber materials only in the sheath.



80. Further, claims 11 and 12 recite a “method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue...” (Ex. 6 at 8:29-38; 60-65). It is my opinion that this refers to a method of using the sternum closure device, not a suture, because a sternum closure goes “about” the margins of tissue (Ex. 6 at Fig. 1) while a suture goes through tissue. Thus, claims 11 and 12 do not refer to a suture and therefore cannot teach all the limitations of the claims of the 446 Patent.

81. Dr. Mukherjee also cites to Chesterfield at column 4, lines 9-23, as disclosing the second fiber forming materials (PET, nylon, or aramid) braided in direct intertwining contact with the first-fiber forming materials (Mukherjee at 16). But that portion of Chesterfield does not explicitly mention nylon, aramid, or PET. Although, that citation does state that “[a]ny number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated” (Ex. 6 at 4:20-24), it does not disclose how these materials are selected or arranged, such that a person of ordinary skill in the art would understand that nylon, aramid, or PET are necessarily disclosed and arranged as claimed in the 446 patent. For example, it does not disclose PET, Nylon, or aramid braided in direct intertwining contact with UHMW PE, as claimed in the 446 Patent.

82. I understand that for any claimed limitation to be inherently disclosed, it must necessarily be disclosed. I see no reason why PET, nylon, or aramid is necessarily disclosed as being braided with UHMW PE in direct intertwining contact in a suture as claimed in the 446 Patent based on Dr. Mukherjee's citation to column 4 of the 575 patent. For example, Dr. Mukherjee provides no explanation as to why one of ordinary skill in the art finds that this statement discloses selecting either PET, nylon, or aramid from the universe of possible yarns. Nor does he provide an explanation of why only one yarn would be picked to be braided with PE in direct intertwining contact when the 575 patent refers to "any combination" of the universe of yarns and does not specify any particular braiding arrangement.

83. I note that when Arthrex was prosecuting an application, which ultimately issued as the 234 patent, Arthrex represented to the Patent & Trademark Office that Chesterfield "does not disclose an example of a braided sheath that includes a blend of both UHMWPE and polyester" (Ex. 13 at DMI041091).

84. Thus, Arthrex's patent counsel agreed with me when it was prosecuting its own patent application.

85. Also, claim 9 of the 446 patent is not anticipated by Chesterfield for the additional reason that Chesterfield does not describe the limitation of claim 9 that the "volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent."

D. If The Claims Of The 446 Patent Are Construed To Mean That “PE” Includes UHMW PE, Then The 446 Patent Is Non-obvious Over Burgess And i) Cohan; ii) The DSM Brochure; And/Or iii) The Harpell Patents

86. My below opinions assume that the claims of the 446 Patent are construed to mean that “PE” includes UHMW PE.

1. It Is My Opinion That Claims 1, 2, 8, 9 and 12 of the 446 Patent Are Not Invalid For Obviousness Over Burgess In View Of Cohan

87. Dr. Mukherjee states that claims 1, 2, 8, and 12 of the 446 Patent are invalid as obviousness over Burgess in view of Cohan. I disagree. Below I discuss the teachings of Burgess and Cohan to one of ordinary skill in the art between 1988 and 1992.

a) The Scope And Content Of Burgess

88. Burgess discloses fishing lines (Ex. 7 at 1), not suture or medical devices.

Burgess discusses certain desirable properties of a fishing line, but does not mention certain suture properties, such as knot security or knot strength (Ex. 7 at 1). Burgess does state that fishing lines “require... non-stretchability” (Ex. 7 at 1). Burgess states that “non-stretchability” is a fishing line requirement, not a preference (Ex. 7 at 1).

89. Burgess further discloses a fishing line that should have a “braided construction” (Ex. 7 at 1). Burgess discloses that some filaments are of “high tensile polythene thread” and other filaments are “polyester and/or nylon” (Ex. 7 at 1). But Burgess does not disclose what kind of “braided construction” he envisioned, how to construct the braid which he references, nor how to use the materials in the “braided construction” he references. For example, Burgess does not disclose whether the polythene thread should be in the core, whether it should be in the sheath alone, or in the sheath with another material. Nor does Burgess disclose whether the polyester and/or nylon alone

should be in the core, whether it should be in the sheath alone, or in the sheath with another material. At no point does Burgess state that the polythene can be in a sheath with another material such as nylon or polyester.

90. In fact, the Burgess disclosure is at most two double-spaced pages. Burgess has no drawings; Burgess provides no working detail or explanation whatever of the braided fishing-line construction which he references. Nor does he provide any description of how to make the “braided construction” to which he refers or the type of equipment that should be used to fabricate the “braided construction” for a fishing line.

91. Burgess discloses the use of high molecular weight polythene in a fishing line. However, one of ordinary skill in the art would know that high molecular weight polythene is a lubricious material with poor knot security and knot tie down characteristics. Burgess does not disclose how to overcome these characteristics of high molecular weight polythene. Notably, Mr. Grafton, former Arthrex employee and developer of FiberWire, also stated that UHMW PE was typically used for fishing line and did not have acceptable knot tie down characteristics for use in sutures (Ex. 14 at 1:14-20). Mr. Grafton also stated that the poor knot slippage of UHMW PE was due to its lubricity (Ex. 12 at 53). Thus, Burgess discloses high molecular weight polythene, which is known to be a lubricous material, but does not describe how to construct an acceptable suture with UHMW PE.

92. I disagree with Dr. Mukherjee about the scope and content of Burgess. Dr. Mukherjee states that “the Burgess application discloses every limitation of claim 1 of the ‘446 patent . . . except that Burgess is not a sterilized suture” (Mukherjee at 17). But Dr. Mukherjee does not provide any analysis as to where the claimed limitations are

found in Burgess. Nor does he explain why Burgess necessarily teaches the braid claimed in the 446 patent, as opposed to some other braid construction. Thus, I disagree with his reading of Burgess.

93. Dr. Mukherjee uses the prosecution history of the 446 patent to support his reading of Burgess. I disagree that the prosecution history supports his analysis. Dr. Mukherjee cites to the Examiner's statement that "Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon," and suggests that the Examiner stated that the "braided construction" of Burgess was the same as the claimed "heterogeneous braid" of yarns in "direct intertwining contact." But the Examiner never said this. Notably, the Examiner never stated that Burgess discloses the claimed "heterogeneous braid" of yarns in "direct intertwining contact." Rather, the Examiner only stated that Burgess disclosed a "braided construction," not any specific braided construction, and then concluded it would have been obvious in light of Burgess to form the claimed invention of then pending claims 21-24. Thus, contrary to Dr. Mukherjee's suggestion, the Examiner never stated that Burgess discloses a heterogeneous braid of UHMW PE and Polyester or nylon in "direct intertwining contact" as claimed in the 446 patent.

b) The Scope And Content Of Cohan

94. Cohan discusses the use of an ultra strong polyethylene fiber in an ophthalmic suture. According to Cohan, the "polyethylene fibers are monofilaments with a ribbon shape." It also describes three monofilaments made from nylon, polypropylene, and polyester. The Cohan article discusses testing each of these monofilaments. The testing results are summarized in Figs. 2-4 and Tables 1-3. Figure 2 shows that a continuous filament of polyethylene has a greater tensile strength at break than the

other materials in the figure and also breaks at a significantly lower elongation. Figure 3 compares the knot pull strength of four fibers and shows that the knot pull strength of PE is higher than the others. Figure 4 describes the results of knot holding strength testing and shows that when comparing the four materials using a knot sequence commonly used in surgery, PE fails at a lower value than the other materials. According to Figure 4, the knot holding strength of PE is lower for certain knot configurations because the PE slips, whereas each of the other three materials break at a higher strength value for these knot configurations.

95. Table 2 of Cohan summarizes knot holding strength for different knot configurations and for four materials. According to Table 2, when the knot configuration was 2=2, PE did not register a value because the knot holding strength was too low (the knot slipped) whereas each of the other three materials reached their knot holding strength without slipping. At the 3=2=1 and 4=1=1 configurations, the PE showed a lower knot holding strength (e.g. 0.35 GPa compared to 0.45, 0.60 & 0.55 at configuration 4=1=1), than the other three materials because, again, the PE was failing by slipping. This knot slippage is not desirable because it means that a knot will not hold. The authors noted that when they tested the PE with more complex (4=4 & 4=4=4) knots, the PE still slipped at 4=4. The PE did not reach its final knot holding strength until a 4=4=4 knot was used. This testing shows to one of ordinary skill in the art between 1988 and 1992 that PE monofilament did not have the knot holding strength of other commonly used monofilaments at the same knot configuration. Also, one of ordinary skill in the art would have known that minimizing the number of knots used to secure a suture in surgery was an important characteristic in suture development.

Therefore, one of ordinary skill in the art would have recognized that Cohan teaches away from using UHMW PE in a suture.

96. Cohan also describes clinical use of the PE monofilament suture. The article states that the PE suture spontaneously untied and at a rate more common than the other materials. The authors explained that this untying was a result of the high flexibility and low friction of the PE. According to the authors, two of the PE fibers acted like “tracks” allowing the third fiber to “slip.” The poor knot tying properties of these UHMW PE monofilaments are a property of the PE itself.

97. Also, Cohan describes the solution for PE’s lower knot holding strength was to tie more complex knots. Cohan does not mention or suggest forming a heterogeneous braid with PE to correct the problem. Thus, one of ordinary skill in the art would have recognized that Cohan teaches away from braiding UHMW PE in a suture.

98. Cohan shows Scanning Electron Micrographs (SEM) of the PE fibers. The SEM’s show lateral connections between the fibrils. The authors also noted in their clinical experience “the occasionally unraveling of microfilaments from the [PE] fiber, sometimes causing irritation until they were removed.” The authors do not explain the cause of the unraveling, or that the possible cause is the fibrils shown in Fig. 1. Further, the authors posit that the use of “gel-spinning” to synthesize the fibers may eliminate the unraveling. But they offer this only as a hypothesis not a proven solution. Because of this recognized, but unsolved problem, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to use UHMW PE in sutures.

99. Cohan states that it was trying to design a suture that was stronger than multifilament silk suture but still has the handling properties of silk. The solution provided by the article is a monofilament PE that requires more complex knots.

100. Dr. Mukherjee makes several statements with respect to Cohan with which I disagree. For example, he states that Cohan teaches a suitable suture made of UHMW PE, and that it is superior. He misinterprets the test results in Table 2. He states that the suture made of UHMW PE had superior knot strength and knot security when compared to the other materials. But Table 2 of Cohan shows that PE had less knot holding strength and less knot security when using comparable knot configurations. In fact, the authors noted that the PE constructs had less knot security because they slipped and failed using certain commonly employed knot configurations.

101. I also disagree with Dr. Mukherjee's statement that Cohan describes a "superior" UMMW PE suture because Cohan's solution to the knot holding strength of UHMW PE was to tie more complex knots. One of ordinary skill in art would recognize this solution was not commercially acceptable to surgeons. A suture that requires a surgeon to tie more complex knots is simply not a "superior" suture.

102. I further disagree with Dr. Mukherjee's statement that Cohan describes a "superior" UHMW PE suture because the authors noted that PE spontaneously untied at a greater rate than the other materials during clinical studies. The unraveled PE led to irritation. Although Cohan posits the hypothesis that "gel-spinning" may eliminate the unraveling, this is an unproven solution to the problem. Thus, given these unresolved issues recognized by Cohan, I do not understand how Dr. Mukherjee opines that the monofilament PE suture of Cohan is a superior suture with superior knot security.

c) The Differences Between Burgess And Cohan And Claim 1 of the 446 Patent Are Significant

103. There are many differences between claim 1 of the 446 patent and the combination of Burgess and Cohan. These differences indicate the non-obviousness of claim 1 of the 446 patent.

104. Claim 1 of the 446 Patent claims a suture. Burgess only describes a fishing line.

105. Claim 1 of the 446 Patent claims a heterogeneous braid where at least one set of yarns from the first group is in direct intertwining contact with at least one yarn from the second group. Burgess does not teach this. In fact, Burgess is entirely silent on the construction of the fishing line or its method of assembly. Thus, Burgess does not teach the braid recited in claim 1 of the 446 Patent.

106. Also, because Burgess does not describe the braided construction he references and does not describe how to make it, Burgess does not enable one skilled in the art between 1988 and 1992 to make and use a suture of claim 1 of the 446 Patent. I do not understand how Dr. Mukherjee considers Burgess to be detailed enough to teach one of ordinary skill in the art in 1992 how to make and use the claimed heterogeneous braid of the 446 Patent, and at the same time opine that the 446 Patent, which is much more detailed than Burgess, does not enable one of skill in the art to make and use the invention claimed in the 446 Patent. Burgess simply does not describe any type of braiding construction, braiding equipment or any braid manufacturing or processing.

107. Likewise, Cohan does not teach the invention of claim 1 of the 446 Patent. Nor does Cohan fill in the gaps left by Burgess. Cohan does not teach a heterogeneous braided suture. Further, the Cohan article does not teach the materials recited in claim

1 of the 446 Patent, where at least one material from the claimed first-fiber group is in direct intertwining contact with a yarn from the claimed second-fiber group.

108. I note here that I disagree with Dr. Mukherjee's opinion that Cohan somehow demonstrates that Mr. Goodwin was incorrect in his response to the patent office when discussing Burgess (Mukherjee at 18). First, Dr. Mukherjee inaccurately paraphrases Mr. Goodwin's statements to the Patent Office. Dr. Mukherjee incorrectly characterizes Mr. Goodwin's statements as "if one were to make a product with high tensile polythene . . . it would be 'unsuitable for use as sutures'" (Mukherjee at 18). Mr. Goodwin never said this. Rather, he said that a medical designer following the teachings of Burgess on how to construct a fishing line with different design criteria than suture would inevitably design an unacceptable suture.

109. Secondly, contrary to Dr. Mukherjee's statements, Cohan shows that Mr. Goodwin was correct. Cohan describes that UHMW PE has poor knot holding strength, which means it is has poor knot strength and poor knot security. Thus, Mr. Goodwin's statements were accurate that knot security and knot strength are a concern and Burgess does not discuss how to address these issues. This is confirmed by Arthrex's 234 patent which explains that fishing line having UHMW PE "does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. 14 at 1:13-20).

d) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with Cohan to Form the Claimed Invention

110. One of ordinary skill in the art would not have been motivated to combine Burgess and Cohan between 1988 and 1992 to form the suture of claim 1 of the 446 Patent. There is no motivation in either Burgess or Cohan to combine them. Also, as

discussed below there is no motivation based on their teachings or the level of skill in the art for several reasons.

111. First, because of the significant differences between Burgess and Cohan and claim 1 of the 446 patent, one of ordinary skill in the art would not have been motivated between 1988 and 1992 to modify Burgess to form the claimed invention. For example, neither describes the claimed heterogeneous suture braid of claim 1 of the 446 Patent, and there is no motivation or suggestion to combine the references to form the claimed braided suture.

112. Second, because Burgess does not describe knot security or knot strength, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to use the teachings of Burgess to make a suture. Knot security and knot strength are two important suture properties. Therefore, Burgess' discussion of different requirements for fishing line and failure to mention knot strength or knot security would cause one of ordinary skill in the art not to be motivated to use Burgess' teachings in designing a suture.

113. Third, Cohan recognizes that monofilament PE has lower knot holding strength and posits overcoming this problem by tying more complex knots. Burgess says nothing about knot holding strength or how to solve the issues raised by Cohan. Thus, one of ordinary skill in the art would not have been motivated to combine Burgess and Cohan to form the claimed invention because he would have focused on trying to resolve the knot holding strength issues raised by Cohan by tying different knots.

114. Fourth, Cohan teaches that monofilament UHMW PE had disadvantages including lower knot holding strength, requiring more complex knots, spontaneous

untying, and unraveling, leading to irritation. Given these problems with the UHMW PE monofilament in Cohan, one of ordinary skill in the art having read Cohan between 1988 and 1992 would not have been motivated to further pursue using UHMW PE without first solving these issues.

115. Fifth, even assuming that one of ordinary skill in the art would have been motivated to pursue the teachings of Cohan, Cohan teaches away from braiding. Cohan teaches trying to design a suture that was stronger than multifilament silk suture, but still had silk's handling properties by tying more complex knots. One of ordinary skill in the art between 1988 and 1992, who had read Cohan, would have focused on monofilaments, tying different types of knots, and eliminating unraveling, not braiding.

116. I have read Dr. Mukherjee's report and Dr. Mukherjee does not specify any motivation for combining the Burgess reference with the Cohan article. He also ignores the differences between the monofilament described in Cohan and the claimed invention of the 446 Patent and the problems noted by Cohan with UHMW PE. Thus, I disagree with his opinion.

117. I note that Dr. Mukherjee states that "it would have been obvious to a person of ordinary skill in the art, in February 1992, to use a heterogeneous braid, such as that disclosed in the Burgess application, for a suture" (Mukherjee at 18). I disagree for the reasons set forth above, but note that the general problem with this statement is that Burgess does not disclose any specific braid construction. Thus, one of ordinary skill in the art reading Burgess in 1992 would not have been able to just simply use a braid disclosed by Burgess as a suture, as Dr. Mukherjee suggests.

e) The Combination of Burgess & Cohan is Cumulative to References The Examiner Considered

118. Dr. Mukherjee relies on Burgess for his obviousness opinions. But Burgess was considered by the Examiner. Dr. Mukherjee's obviousness opinions with respect to Burgess appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application claims. But the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, e.g. Abstract and p. 8). Therefore, the Examiner considered Burgess and a reference disclosing the use of UHMW PE in a suture (Ex. 17 at DMI000596). Consequently, to the extent that Dr. Mukherjee's obviousness opinions rely on Burgess and other references showing UHMW PE in sutures, his opinions are based on information already considered and rejected by the Examiner. Thus, the Examiner's issuance of the 446 patent over these references confirms my opinions of non-obviousness.

f) Secondary Considerations of Non-obviousness

119. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent have been commercially successful and have been praised by Arthrex. This indicates their non-obviousness.

g) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess in light of Cohan

120. Based on (i) the scope and teachings of Burgess and Cohan; (ii) the differences between claim 1 of the 446 patent and Burgess and Cohan; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-obviousness; and (v) Burgess and

Cohan being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obvious.

121. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 “is attached to a needle” (Ex. 2 at 9:11-12). Because claims 2 and 12 contain all of the limitations of claim 1 plus an additional limitation, they are non-obvious for the same reasons as claim 1.

122. Claim 8 of the 446 patent recites that the “second set of yarns is PET” (Ex. 2 at 10:7-8), but is otherwise the same as claim 1. In order to show the obviousness of claim 8, the references must show a suture having all of the limitations of claim 1 and the claimed second yarn being PET, as opposed to Nylon, PET, or aramid as recited in claim 1. The art relied upon by Dr. Mukherjee does not disclose the claimed second yarn as being PET for the reasons set forth above with respect to claim 1. Accordingly, except for my opinions regarding Nylon and aramid, my opinions described above with reference to Burgess and Cohan apply to claim 8.

123. Claim 9 of the 446 patent is also non-obvious for the same reasons as claim 1 and for additional reasons. Claim 9 of the 446 patent recites that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent” (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is non-obvious for this additional reason.

2. It Is My Opinion That Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & The DSM Brochure

124. Claims 1, 2, 8, 9, and 12 of the 446 patent are not obvious over Burgess in light of the DSM brochure. I have described the scope and content of Burgess and the DSM

brochure above. Also, I have described the differences between Burgess and the DSM brochure and the sutures of claims 1, 2, 8, 9, and 12 above. Those discussions apply here as well.

a) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with the DSM Brochure to Form Claim 1 of the 446 Patent

125. One of ordinary skill in the art from 1988-1992 would not have been motivated to combine Burgess and the DSM brochure to form the claimed invention of the 446 Patent for many reasons. There is no motivation to combine them in such a way so as to form the claimed suture of the 446 patent.

126. First, because of the significant differences between the invention claimed in the 446 patent and Burgess and the DSM brochure, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to combine them to form the claimed invention. For example, because neither describes a heterogeneous braid of yarns in direct intertwining contact, as claimed in the 446 Patent, there is no motivation or suggestion to combine the references to form the claimed heterogeneous braid.

Burgess does not describe how to combine the polyester and/or nylon with UHMW PE. The DSM brochure does not describe combining yarns at all or how to construct any type of suture. Thus, because of the significant differences between the invention claimed in the 446 patent and these references and the lack of any guidance as to how or why to make a braid, there is no motivation or suggestion as to how to combine the UHMW PE with nylon and/or polyester to form a heterogeneous braid in direct intertwining contact as claimed in the 446 Patent.

127. Second, because Burgess does not describe knot security or knot strength and the DSM brochure touts the high knot strength of certain Dyneema fibers, one of

ordinary skill in the art between 1988 and 1992 would not have been motivated to use the teachings of the DSM brochure with the teachings of Burgess. One of ordinary skill in the art in 1992 would have been motivated to explore using just the UHMW PE fibers taught by the Dyneema brochure to take advantage of the touted knot strength. There is no discussion in either reference of how braiding affects knot strength. In my opinion, one of ordinary skill in the art would not have attempted to braid UHMW PE with nylon or PET based on these references because the resulting effect on knot strength was not known.

128. Third, one of ordinary skill in the art would not have been motivated to combine the DSM brochure and Burgess to form the claimed suture of the 446 patent because he would have known that the UHMW PE disclosed in the DSM brochure was lubricious and therefore would not provide good knot security. Neither the DSM brochure nor Burgess discuss how to address UHMW PE's lubricity and form a suitable suture. Thus, absent a teaching addressing this issue, one of ordinary skill in the art would not have been motivated to combine Burgess and the DSM brochure to arrive at the claimed invention.

129. I note that Dr. Mukherjee does not provide any motivation or suggestion to combine Burgess and the DSM brochure to form the claimed invention. Dr. Mukherjee opines that one of ordinary skill in the art in 1992 would have "been motivated to take the recommendation of the DSM brochure to use Dyneema in a suture application and to combine it in a braided suture with polyester/and or nylon, as in Burgess." But Burgess is not a "suture application." Therefore, even if one of ordinary skill in the art would have been motivated to use the Dyneema described in the DSM brochure in

“suture application,” it would not be with Burgess. Further, even if one was motivated to use the Dyneema with the teachings of Burgess, Burgess does not describe any braid construction. Therefore, there is no motivation or suggestion to form the claimed invention.

b) The Combination of Burgess & the DSM Brochure is Cumulative to References The Examiner Considered

130. Dr. Mukherjee’s obviousness opinions with respect to Burgess and the DSM Brochure appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application. But, as described above with reference to Cohan, the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, *e.g.* Abstract and p. 8). Thus, Burgess and the DSM Brochure are cumulative to the references considered by the Examiner, and the Examiner’s issuance of the 446 patent over these references confirms my opinions of non-obviousness.

c) Secondary Considerations of Non-obviousness

131. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent are non-obvious and have been praised by Arthrex. This indicative of their non-obviousness.

d) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & the DSM Brochure

132. Based on (i) the scope and teachings of Burgess and the DSM brochure; (ii) the differences between claim 1 of the 446 patent and Burgess and the DSM brochure; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-

obviousness; (v) and Burgess and the DSM brochure being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obvious.

133. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 “is attached to a needle” (Ex. 2 at 9:11-12). Thus, claims 2 and 12 of the 446 patent are non-obvious for the same reasons as claim 1 of the 446 patent. Claim 8 of the 446 patent recites that the “second set of yarns is PET” (Ex. 2 at 10:7-8). As described above, neither Burgess nor the DSM brochure disclose PET braided as claimed. Thus, with this exception that claim 1 recites that the second fiber forming material could be nylon, aramid, or PET, my opinions described above with reference to Burgess and the DSM brochure apply to claim 8 as well, and it is non-obvious.

134. Claim 9 of the 446 patent are also non-obvious for the same reasons as claims 1 and for additional reasons. Claim 9 of the 446 patent recites that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent” (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is for this additional reason non-obvious.

3. Claims 1, 2, 8, 9, and 12 of the 446 Patent Are not invalid For Obviousness Over Burgess and the Harpell Patents

a) The Scope and Content of Burgess & the Harpell patents

135. The scope and content of Burgess is discussed above. Below, I discuss the teachings of the Harpell patents to one of ordinary skill between 1988 and 1992.

Because Dr. Mukherjee has not differentiated between the Harpell patents and they appear to be substantially the same, I refer to the 392 Harpell patent for convenience.

136. The Harpell patents teach that extended chain polyolefin fibers, such as those formed from polyethylene and polypropylene (Ex. 9 at 1:8-9), have two disadvantages. First, the Harpell patents describe extended chain polyolefin fibers as having “low transverse strengths, with a corresponding tendency of the fibers to fibrillate especially when subjected to abrasion or self-abrasion, particularly when twisted or processed into a fabric” (Ex. 9 at 1:29-32). Second, the Harpell patents state that extended chain polyolefin fibers “have poor adhesion to most matrix materials” (Ex. 9 at 1:38). According to the Harpell patents, these disadvantages “limit the usefulness of these fibers in composite structures” (Ex. 9 at 1:39).

137. In order to overcome these disadvantageous, the Harpell patent teaches coating the extended chain polyethylene or polypropylene fibers with a “polyethylene, polypropylene, ethylene copolymer or propylene copolymer” (Ex. 9 at 1:43-45). The Harpell patents teach that coating the fibers “reduces the tendency of the fibers to fibrillate, increases their transverse strength, enables the fibers to be used in composite structures alone or with a variety of matrix materials and achieves these results without any significant loss of the tenacity and modulus values for the fiber alone (Ex. 9 at 1:46-51).

**b) The Difference Between Burgess & The Harpell Patents
And Claim 1 of the 446 Patent**

138. The differences between claim 1 of the 446 patent and Burgess were discussed above. The Harpell patents are also different than claim 1 of the 446 patent. Claim 1 of the 446 patent claims a heterogeneous braid of yarns in direct intertwining contact. The Harpell patents do not disclose a heterogeneous braided suture, let alone direct intertwining contact of two dissimilar yarns. Claim 1 of the 446 patent claims a

heterogeneous braid of certain materials. The Harpell patents do not disclose a braid having the claimed first and second fiber-forming yarns. Thus, both the Burgess and Harpell references do not contain numerous features recited in the claims of the 446 patent.

c) One of Ordinary Skill in the Art Would Not Have Been Motivated to Combine Burgess with the Harpell patents to Form Claim 1 of the 446 Patent

139. There is no motivation or suggestion to modify either Burgess or the Harpell patents in such a way so as to form the suture of claim 1 of the 446 patent.

140. Given the significant differences between the references and claim 1 of the 446 Patent, one of ordinary skill in the art would not have been motivated to combine the references to form the claimed suture. Neither Burgess nor the Harpell patents describe how to braid the materials in direct intertwining contact as recited in claim 1 of the 446 patent. The Burgess reference offers no specificity about the construction of the braid other than to use the term "braid." This hollow disclosure does not motivate one of ordinary skill in the art to use it in combination with the Harpell patents. Consequently, there is nothing in these references to teach one of ordinary skill in the art to make the invention of claim 1 of the 446 patent.

141. One of ordinary skill in the art would not have been motivated to combine the Harpell patents and Burgess for the additional reason that neither of these references describe knot security or knot strength. Knot security and knot strength are two characteristics important to a suture developer. Therefore, because there is no mention of these important characteristics, one of ordinary skill in the art would not have been motivated to use them together to improve suture properties.

142. Also, one of ordinary skill in the art would not have been motivated to combine Burgess and the Harpell patents because the Harpell patents describe coating fibers to reduce fibrillation. The Harpell patents describe certain fibers and coating them in the range of 0.1% to 200% by weight of fiber in order to reduce fibrillation (Ex. 10 at 4:40-42). With respect to suture applications, the Harpell patents disclose that a “preferred coating amount is between about 10 and about 50%, by weight of fiber” (Ex. 10 at 4:44-45). Therefore, rather than forming the claimed suture, one of ordinary skill in the art having read the Harpell patents between 1988-1992 would have been motivated to apply different coatings, in various amounts, and in different ways, to different UHMW PE or extended chain polypropylene fibers to determine whether the fibrillations could be reduced, not to form braided heterogeneous sutures.

d) The Combination of Burgess & the Harpell Patents is Cumulative to References The Examiner Considered

143. Dr. Mukherjee’s obviousness opinions with respect to Burgess and the Harpell patents appear to be based on the incorrect premise that the Examiner was not aware of a reference showing that UHMW PE could be used in a suture, and if he was, he would have combined it with Burgess to reject the 446 patent application. But, as described above with reference to Cohan, the Examiner already considered a reference that explicitly discloses using UHMW PE in a suture (Ex. 15 at PCT application WO 86/00020 at DMI000150-179, *e.g.* Abstract and p. 8). Thus, Burgess and the Harpell patents are cumulative to the references considered by the Examiner, and the Examiner’s issuance of the 446 patent over these references confirms my opinions of non-obviousness.

e) Secondary Considerations of Non-obviousness

144. As explained above, the inventions of claims 1, 2, 8, 9, and 12 of the 446 patent are non-obvious and have been praised by Arthrex. This indicates their non-obviousness.

f) Claims 1, 2, 8, 9, and 12 of the 446 Patent Are Not Obvious Over Burgess & the Harpell Patents

145. Based on (i) the scope and teachings of Burgess and the Harpell patents; (ii) the differences between claim 1 of the 446 patent and Burgess and the Harpell patents; (iii) the level of ordinary skill in the art; (iv) the secondary considerations of non-obviousness; and (v) Burgess and the Harpell patents being cumulative to the information considered by the Examiner, claim 1 of the 446 patent is non-obviousness.

146. Claims 2 and 12 of the 446 patent recite the additional limitation that the suture of claim 1 “is attached to a needle” (Ex. 2 at 9:11-12). Thus, claims 2 and 12 of the 446 patent are non-obvious for the same reasons as claim 1 of the 446 patent.

147. Claim 8 of the 446 patent recites that the “second set of yarns is PET” (Ex. 2 at 10:7-8). As described above, neither Burgess nor the Harpell patents disclose PET braided as claimed. Thus, with this exception that claim 1 recites that the second fiber forming material could be nylon, aramid, or PET, my opinions described above with reference to Burgess and the Harpell patents apply to claim 8 as well, and it is non-obvious.

148. Claim 9 of the 446 patent is also non-obvious for the same reasons as claim 1 and for additional reasons. Claim 9 of the 446 patent recites that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent” (Ex. 2 at 10:9-11). Dr. Mukherjee has pointed to nothing that discloses this

limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is for this additional reason non-obvious.

VII. It Is My Opinion That All of the Claims of the 446 Patent Are Not Invalid For Failing To Satisfy The Written Description & Enablement Requirements

A. The 446 Patent is Not Invalid for Failing to Satisfy the Written Description Standard

149. Dr. Mukherjee opines that all of the claims of the 446 Patent are invalid for failing to satisfy the written description standard. According to Dr. Mukherjee, the 446 Patent “does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE” (Mukherjee at 22). Since this is the only issue that Dr. Mukherjee has raised with respect to written description, it is the only one that I address. I disagree with his opinion. The 446 Patent does reasonably convey to one of skill in the art that the inventors had possession of the claimed suture with UHMW PE as the first-fiber forming material.

150. My opinion is supported by the 446 Patent’s text. The 446 Patent specifically claims “PE.” Further, the 446 Patent expressly describes “polyethylene (PE)” (Ex. 2 at 4:27,30). One of skill in the art would have known that “PE” means “polyethylene” and means all polymers made from ethylene. PE is the generic name for all types of PE, including UHMW PE. In 1987, the Encyclopedia of Polymer Science and Engineering 2nd edition volume 10 recognized polyethylene as the “common (source-based)” name for all polymers made from ethylene (Ex. 18). Further, the IUPAC officially recognized that PE is the accepted abbreviation for all types of PE (Ex. 19). Thus, one of skill in the art would have known that “PE” or “polyethylene” as used in the 446 Patent means all polymers from ethylene including UHMW PE.

151. The 446 Patent's description of PE is consistent with all types of PE. The 446 Patent states that in a preferred embodiment the first set of yarns act as lubricating yarns (Ex. 2 at 4:11-12). PE including UHMW PE is a lubricious yarn (Ex. 12 at 52-53). Cohan shows that one of skill in the art would have known that UHMW PE is a lubricious material because the UHMW PE used in the Cohan article slipped and required complex knot configurations in order to evaluate the material's knot hold strength. Also, the 446 Patent states that the first set of yarns may be derived from "non-absorbable polymers." PE including UHMW PE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber forming materials (Ex. 2 at 4:30-32). PE including UHMW PE is a fiber forming material. Therefore, the 446 Patent's description of PE is consistent with the meaning of PE and does not exclude UHMW PE.

152. My opinion that "PE" as used in the 446 Patent includes UHMW PE is supported by Arthrex's use of the term "polyethylene." I note that Arthrex described the UHMW PE used in FiberWire and other sutures as "polyethylene" without specifically calling out that it is UHMW PE (Ex. 20 at ARM002188-89; Ex. 21 at ARM02184-87; Ex. 22 at DMI Ex. 343). Also, I note that Cohan refers to ultrastrong polyethylene in the first instance but thereafter Cohan uses the terms ultrastrong polyethylene and polyethylene interchangeably to describe the suture materials. Further, my opinion that one of skill in the art would understand PE to include UHMW PE is confirmed by the DSM brochure. The brochure teaches that "polyethylene" properties cover the range from 1 N/tex specific strength and 25 N/tex specific modulus to 3.5 N/tex specific strength and 150 N/tex specific modulus. It also notes that Dyneema SK60 falls within this range at 2.7

N/tex and 90 N/tex. Thus, the DSM brochure refers to UHMW PE as polyethylene, and those skilled in the art do in fact refer to UHMW PE as polyethylene, just as the inventors did in the 446 Patent.

153. My opinion is further supported by the prosecution history of the 446 patent. Burgess discloses high molecular weight polythene (Ex. 7 at 1:13-14). During the prosecution history, Mr. Goodwin referred to the high molecular weight polythene disclosed in Burgess generically as “polythene,” which is the English term for polyethylene (Ex. 17 at DMI000595). Likewise, the Examiner twice referred to the high molecular weight polythene disclosed in Burgess generically as “polythene” (Ex. 17 at DMI000601). Notably, both the Examiner and the applicants referred to high molecular weight polythene by its generic or common, source-based name.

154. I disagree with Dr. Mukherjee that PE does not include UHMW PE to one of ordinary skill unless UHMW PE is specifically named. This statement makes no sense. It assumes that the well-accepted definition of PE is wrong and excludes UHMW PE. I know of no change in the well-accepted scientific naming conventions. While some authors may specifically refer to UHMW PE, my experience is that they do so when they want to emphasize the characteristics of UHMW PE as compared to PE. Here, the inventors of the 446 Patent had no reason to specifically refer to UHMW PE. PE was referred to as being lubricous. UHMW PE is lubricous. Therefore, there was no particular reason for the inventors to recite both PE and UHMW PE. Notably, the inventors referred to other materials such as nylon, aramid, PET, PTFE, PETFE, FEP, and PP generically as well. Therefore, the term PE was not treated any differently than the other materials. I note that Dr. Mukherjee does not read any other generic terms to

be limited to a certain range of the generic material. Further, Dr. Mukherjee equates the generic term “polypropylene” with a specific polypropylene, hard elastic polypropylene in the 688 patent. Thus, Dr. Mukherjee appears to read the generic term PE as limited, but not the other generic materials named in the 446 patent.

155. Dr. Mukherjee also states that the UHMW PE is not disclosed in the 446 Patent because PE is described in the 446 Patent as being “weak” which he states is inconsistent with UHMW PE (Mukherjee at 23). I disagree with both assertions. First, I disagree that the 446 Patent describes the first set of yarns being “weak.” The 446 Patent never describes the first fiber-forming yarns as “weak.” Instead, the 446 Patent, in one embodiment, describes the first set of yarns as lubricating yarns to “improve the overall pliability or compliance and surface lubricity of the heterogeneous braid” (Ex. 2 at 4:12-14). Dr. Mukherjee’s statement that the first set of yarns are described as being too weak is just incorrect. Notably, in the background of the 446 patent it describes a “highly pliable braid” made from “highly lubricous polymers” in a “traditional manner” as being “relatively weak and unusable” in most cases (Ex. 2 at 2:22-25). But this is not a description of the highly lubricous *material* as “weak.” Rather, it is a description of a certain *braid* – a *highly pliable braid* of just highly lubricous material -- as being weak, which is what one of ordinary skill would expect, because the material will likely slip (Ex. 8). I understand that Mr. Grafton constructed a braid of UHMW PE and had this very problem (Ex. 12. at 53-54).

156. Dr. Mukherjee’s opinion appears to be based on a misunderstanding of the invention described in the 446 Patent. He appears to equate lubricity with weakness and reads the 446 Patent, as describing braiding a weak yarn with a strong yarn. But

this is incorrect. The 446 Patent teaches, among other things, that a lubricious yarn can be braided with another yarn of different properties (e.g., different lubricity, strength) to yield a braid that benefits from the lubricity of the first material and the strength of the second material. One of skill in the art, reading the 446 Patent, would understand that a braid of UHMW PE and PET would benefit from the lubricity of the UHMWPE and the strength of the PET. Dr. Mukherjee appears to assume that because in some embodiments the 446 Patent describes the first set of yarns as being for lubricity and the second set of yarns being for adding strength, that the first set of yarns must be weak. That is not stated in the 446 Patent. Nor would one of skill in the art read “weakness” into the 446 Patent.

157. I also disagree with Dr. Mukherjee’s assertion that UHMW PE is not “weak.” Although Dr. Mukherjee refers to yarns as being “weak,” he does not describe in what sense they are weak. Thus, I am not sure what he means by weak. But, I note that Cohan described the tendency of monofilament UHMW PE to slip and the need for more complex knots when tying UHMW PE. In that sense, UHMW PE could be considered weak. I note that Arthrex made similar statements when applying for its own patent (Ex. 14 at 1:13-20). Arthrex reported in its 234 patent that UHMW PE “does not have acceptable knot tie down characteristics for use in surgical applications” (Ex. 14 at 1:20-21). Thus, with respect to knot hold, knot tie, and knot security UHMW PE may be considered “weak.”

B. It Is My Opinion That 446 Patent Claims Are Not Invalid For Failing To Satisfy The Enablement Requirement

158. Dr. Mukherjee opines that when “viewed from the perspective of a person skilled in the art in February 1992, the 446 Patent does not teach a person how to make and

use a surgical suture including UHMWPE without having to resort to undue experimentation (Mukherjee at 25). I disagree. It is my opinion that the 446 Patent does teach a person of skill in the art in 1992 how to make and use the claimed surgical suture without having to resort to undue experimentation.

159. I note that Dr. Mukherjee only discusses whether a person of skill in the art could make the invention, and he does not describe whether they could “use” the invention. Therefore, I will only address the issue of making. For the reasons explained above, I disagree with Dr. Mukherjee regarding whether the 446 Patent disclosed UHMW PE to one of skill in the art. The 446 Patent describes how to make the claimed suture without undue experimentation. The 446 Patent states that the “heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures” (Ex. 2 at 4:60-62). The 446 Patent also describes a “plan view” of a yarn carrier layout for a carrier braiding machine for braiding (Ex. 2 at Fig. 1 and 4: 63-66). The 446 Patent then describes how to make a braid of two yarns by moving the braiding machine carriers (Ex. 2 at 4:67-5:26) and forming a braid that is in direct intertwining contact. The yarns claimed in the 446 Patent, including UHMW PE, can be braided on a conventional carrier braiding machine described in the 446 Patent. One of ordinary skill in the art in 1992 would have known after reading the 446 Patent how to braid UHMW PE with either nylon, aramid, or PET to form the claimed invention. My opinion is supported by Pearsalls, I note that Pearsalls makes FiberWire by braiding UHMW PE on a conventional braiding machine with PET.

160. The 446 Patent also provides specific guidance on manufacturing certain preferred embodiments. The 446 Patent notes that “yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal” (Ex. 2 at 5:50-52). According to the 446 Patent, the “equilibration of yarn elongation may prevent irregularities, for example, core popping” (Ex. 2 at 5:53-54). Also, the 446 Patent advises that the “number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g., the tendency of the core popping and overall braid smoothness” (Ex. 2 at 5:56-61). Adjusting braiding tension is a routine, common practice to one of skill in the art and something that is generally adjusted when constructing any braids. Thus, with this guidance provided by the 446 Patent one of skill in the art could have made a braid of UHMW PE with PET, aramid, or nylon.

161. Further, the 446 Patent describes two preferred embodiments. In the first, it discloses that a braid of 70 denier PET and 110 denier PTFE (Ex. 2 at 7:38-39). It also discloses that for that braid a 32 pick gear with a spring tension of 0.009” for the PET carriers and no spring tension with the PTFE carriers (Ex. 2 at 7:49-50). Also, it discloses a second embodiment of 75.5% PET and 24.5% PTFE with the same spring tension. Thus, the 446 Patent clearly advised one of skill in the art---what he already knew—to adjust the yarn tension when braiding to accommodate for the different yarn properties, including elongation characteristics.

162. The 446 Patent also describes several other conventional suture manufacturing processes that were well known to one of skill in the art in 1992, including,

scouring to remove machine oils and lubricants, stretching “*preferably*” at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns, annealing to improve dimensional stability, coating, and sterilization (Ex. 2 at 5:61-6:30). All of these general techniques were known to one of skill in the art in 1992. They were employed to make sutures. Based on the teachings set forth in the 446 patent, one of skill in the art could easily have adapted the known braiding techniques to braid UHMW PE with PET, nylon, or aramid to form the claimed invention without undue experimentation.

163. Dr. Mukherjee appears to provide two reasons why one of skill in the art in 1992 could not after reading the 446 Patent make a braid of UHMW PE with either nylon, PET, or aramid. He states that “UHMWPE is known to be extremely strong and to have low elongation” and that “[t]hese specialized properties must be taken into account when including UHMWPE in a braided structure as they will have an effect on the manufacturing process” (Mukherjee at 26). He also states that because “UHMWPE has such low elongation ... [it]presents certain tensioning problems” (Mukherjee at 26). But Dr. Mukherjee does not describe what those “tensioning problems” are; why they are any different than braiding any two materials whose elongations do not match; and why it is beyond the routine skill in the art to adjust the braiding machine (e.g., adjust the braid tensions of the different yarns) to compensate for the differences in elongation. In any event, the 446 Patent specifically disclosed braiding and adjusting the “yarn tension” to compensate for different material elongation. Thus, the 446 Patent specifically addresses the “elongation” issue that Dr. Mukherjee refers to and describes how to solve it. A person of skill in the art would know that when operating a braiding

machine, the tension of the yarns has to be adjusted to compensate for the elongation of the yarns. Braiding yarns with conventional braiders was well-known in 1992. There is nothing peculiar about braiding UHMW PE that would not have been known to the person of ordinary skill. It was within the routine work of a person of skill to adjust braiding tension.

164. My opinion is supported by the testimony of Mr. Hallet from Pearsalls. He testified that Pearsalls uses all known conventional equipment to braid UHMW PE. For example, Pearsalls has had the Hubourns braider that it uses to make FiberWire for about 55 years (Ex. 23 at 71:8-12). Further, Mr. Hallet described the braiding of FiberWire on conventional carrier braiding machines and adjusting the tension based on the yarns (Ex. 23 at 63:5-70:10). My opinion is further supported by the testimony of Arthrex's manufacturing witness, Mr. Dreyfuss, who said that, when Arthrex began developing FiberWire™, braiding the UHMW PE required only "normal development" and was done with "ordinary" braiding techniques.⁵ Mr. Hallet testified that the tension had to be adjusted for various size FiberWire. That comports with my understanding of what was known to one of skill in the art in 1992 and why the 446 Patent would not need to specifically disclose braiding parameters specific to a certain size UHMW PE to be braided with another specific material on a specific machine.

⁵ [21:13 Q. When Arthrex began developing the FiberWire
 21:14 suture, did it have any problems braiding the ultra high
 21:15 molecular weight polyethylene?
 21:16 A. I'm sorry; could you read that back?
 21:17 (The requested portion of the record was read.)
 21:18 A. Not that I'm aware of.
 21:19 Q. It didn't -- The ultra high molecular weight
 21:20 polyethylene didn't require any special braiding
 21:21 techniques to produce a suture?
 21:22 A. Nothing out of the ordinary.
 21:23 Q. What does that mean?
 21:24 A. Normal development. (Ex. 24)

165. To the extent that Dr. Mukherjee is stating that the 446 Patent should have disclosed more particular details, I disagree because such details are manufacturing details related to making a commercial product that I understand need not be disclosed. For example, providing a specific braiding tension is somewhat meaningless because it is so specific. It is dependent on the type of machine, the number of yarns, the material of the yarns being braided, the size of the yarns, the denier of the yarns and other factors. There are many variables in setting the braiding tension that persons skilled in the art are familiar with that there was no reason for the 446 Patent to specifically disclose a specific braiding tension.

166. Dr. Mukherjee also opines that the one of skill in the art could not after reading the 446 patent make the claimed invention with UHMW PE because "UHMW PE reacts differently to heat than any of the disclosed second fiber-forming materials" which affects the braid's reaction to hot stretching and the 446 Patent does not advise whether hot stretching is necessary when using UHMWPE. I do not fully understand Dr. Mukherjee's opinion, so I am not able to respond. First of all, he does not define "hot stretching" so it is not clear what he means by the term. Further, it is not clear whether he believes that hot stretching a braid of UHMW PE is necessary, unnecessary, or necessary under certain parameters. Nor does he sufficiently identify what disclosure is allegedly missing from the 446 Patent so that, according to his opinion, one of skill in the art could not make the claimed suture in the 446 patent without undue experimentation.

167. Also, I note that Arthrex has a patent claiming sutures that claims a cover formed of a plurality of braided fibers which include UHMW PE (Ex. 14 at 3:13-17). I note that

Arthrex's patent provides no description of how to make a suture and certainly no description of what Dr. Mukherjee contends is absent from the 446 Patent. For example, Arthrex's 234 patent discloses two suture braids made on 16 and 12 carrier braiders with polyester and Dyneema, but does not disclose any braiding tensions, whether hot stretching is needed, or what temperatures at which to conduct any stretching, or how UHMW PE reacts to heat. If Arthrex's patent satisfies the enablement standard, I am not sure why the 446 Patent does not.

VIII. The Inventors Reduced the Claimed Invention to Practice

168. Generally, I understand that in order for a claimed invention to be actually reduced to practice, the invention must have been made and evaluated so that the inventors knew that it would work for its intended purpose.

169. I have reviewed Dr. Steckel's deposition transcript, Dr. Jamiolkowski's testimony, and Dr. Steckel's lab notebooks. It is my opinion that the inventors had made and tested a braided suture that was suitable for its intended purpose and had proved the concept of the invention at least as early as February 1989 and December 1989. I understand from Dr. Steckel's testimony that he referred to some of the work that led to the 446 patent as "Composite Braid Evaluation" or "CBE" (Ex. 25 at 135:1-21).

170. Dr. Steckel's notebook describes conception of the claimed invention at least as early as June 6, 1988 (Ex. 26 at DMI002617). Dr. Steckel describes his idea as "[a] preliminary evaluation of composite braids, *i.e.*, braided sutures constructed of two or more fiber types designed to realize the beneficial properties of each polymer" (Ex. 26 at DMI002617). He further states that the composite sutures to be evaluated included carrier blended "PET/PTFE" and "PET/PP" yarns in which blending occurs when two different yarns reside on different carriers during the braiding operation. (Ex. 26 at

DMI002617). Thus, at least as early as June 6, 1988, he had described the broad concept of a heterogeneous braided suture with two yarns in direct intertwining contact and provided two specific examples of braiding PET/PTFE and PET/PP (see *also* Ex. 27 at 99:7-25; 100:20-23; 102:10-17; 127:12-21; Ex. 25 at 159:6-23; 160:17-22; 161:4-10).

171. Dr. Steckel's notebook and testimony confirm that he built a suture braid as claimed in the 446 patent at least as early as June 6, 1988 (Ex. 26 at DMI002618; Ex. 27 at 127:12-128:21; Ex. 25 at 218:21-25). For example, Dr. Steckel built the CBE-15 prototype on June 6, 1988 with a carrier braider ("CB") (Ex. 26 at DMI002618). The CBE-15 braid was made from braid of 51% PET and 49% PTFE by volume (Ex. 26 at DMI002618). The yarns used to construct the CBE-15 braid are specified on page DMI002619 of Dr. Steckel's notebook (Ex. 26 at DMI002619). In June 1988, Dr. Steckel performed basic suture testing on CBE-15 including straight tensile and knot tensile testing (Ex. 25 at 219-220). Thus, at least as early as June 6, 1988, Dr. Steckel had conceived of the idea of braiding two materials, of the type claimed in the 446 patent, in direct intertwining contact to form a suture and had made a suture having these characteristics.

172. Dr. Steckel's notebook describes prototypes that he had constructed and tested as least as early as February 2, 1989 (Ex. 26 at DMI002635-38; Ex. 25 at 220-221). He had constructed PET/PTFE carrier braided sutures designated as CBE-15 having PET and PTFE yarns which were carrier braided in direct intertwining contact (Ex. 26 at DMI2635-36; Ex. 25 at 222-223). Dr. Steckel testified that "full characterization" of the braids had been completed at least as early as February 1989 (Ex. 25 at 218-219). His

notebook describes various testing that he performed on the braided sutures (Ex. 26 at DMI002637; Ex. 25 at 222).

173. Dr. Steckel had constructed and evaluated a suture that is within the scope of claims 1, 8, and 9 of the 446 patent at least as early as February 1989 (except it was not sterile). He had built a "heterogeneous suture" of PTFE and PET yarns. The PTFE and PET yarns were "continuous and discrete yarns" as claimed in the 446 patent (Ex. 2 at 8:65). They were also in "direct intertwining contact" because they were carrier braided (Ex. 2 at 8:67). The PTFE yarns were a "plurality of filaments of a first fiber-forming material," and the PET yarns were "a plurality of filaments of a second fiber-forming material" as claimed (Ex. 2 at 9:1-8). The volume fraction of the PTFE, the lubricating yarn, was 51% by volume (Ex. 26 at DMI002636). Further, Dr. Steckel had tested and evaluated the sutures. Therefore, he had reduced the sutures of claims 1, 8, and 9 to practice at least as early as February 1989.

174. I also note that Dr. Steckel built and tested prototypes in December 1989 (Ex. 26 at DMI2665-67). These prototypes were carrier blends of PTFE and PET yarns that were braided in direct intertwining contact (Ex. 26 at DMI2665). The specific braiding sequence is shown in Dr. Steckel's notebook (Ex. 26 at DMI2665). Similar to the prior PTFE/PET braids, these braids are also within the scope of claims 1, 8 and 9 of the 446 patent. Dr. Steckel evaluated the December 1989 prototypes and noted that the prototypes offered "exceptional handling properties for a braided suture" (Ex. 26 at DMI002665; Ex. 25 at 235:1-7). He also found that these prototypes "ranked better" in "handling properties" and knot-tie down relative to silk and Ethibond (Ex. 26 at DMI002666; Ex. 25 at 236:1-12). As he explained, the bending modulus of the

composite PTFE/PET suture braid was lower than silk and Ethibond (Ex. 26 at DMI002666-67). This means that the PTFE/PET braid was more flexible than silk and Ethibond. Dr. Steckel further noted that the intrinsic tensile and knot strength of the composite braid were 87 ksi. and 48 ksi. respectively. Based on Dr. Steckel's construction and evaluations, it is my opinion that Dr. Steckel had reduced to practice the claimed invention at least as early December 1989.

175. Dr. Mukherjee has opined that the inventors of the 446 patent did not actually reduce the invention to practice in February 1989 or prior to the February 19, 1992 filing date of the application. I disagree. The inventors had constructed a suture that they knew would work for its intended purpose.

176. Dr. Mukherjee opines that the inventors never actually reduced the claimed invention to practice because they did not construct a "sterile" suture (Mukherjee at 27-28). I first note that Dr. Mukherjee points to no specific testimony that says all of Dr. Steckel's braid constructions were not sterile. Dr. Mukherjee states that there was no reduction to practice because sterilization, generally, "*can* have a substantial effect on the braid properties" (Mukherjee at 28). But Dr. Mukherjee recognizes that this is only a possibility, not a fact. Also, Dr. Mukherjee provides no basis that this statement applies to any of the materials listed in the 446 patent. Further, he does not explain what effect he is referring to or under what conditions such effects may happen. Thus, even if the braids constructed by Dr. Steckel were not sterile, it is my opinion that the inventors had reduced the claimed invention to practice because the inventors had constructed and tested the claimed suture and knew that it would work as a suture for its intended purpose.

177. I also disagree with Dr. Mukherjee that sterilization was needed to reduce the claimed invention to practice because sterilization of medical devices including sutures were known processes that date well before the inventors work in 1988. The typical sterilization processes are gamma sterilization and ethylene oxide. Notably, the 446 Patent refers to both types of sterilization (Ex. 2 at 6:21-29). One of ordinary skill in the art would have been aware of both methods of sterilization and the parameters for sterilizing sutures and the materials claimed in the 446 patent. Further, one of ordinary skill in the art between 1988 and 1992 would have known that sterilization under normal conditions would not have had any substantial affect on braid properties, other than sterilization. Thus, there was no need for the 446 patent inventors to sterilize the sutures that they had constructed in order to show that they would work for their intended purpose and to prove the concept of their invention.

178. I further disagree with Dr. Mukherjee that sterilization was needed to reduce the claimed invention to practice because typically sterilization is done for product commercialization, not proof of concept. A suture designer would generally not sterilize his work unless it was to be tested in the body, or it involved product commercialization. Sterilization is basically a commercialization step that was not needed here to prove the concept of the invention claimed in the 446 patent. Requiring the inventor to sterilize the braided suture constructs would basically require him to make a commercial product and sterilize it in its packaging because typically sutures are sterilized in the packaging. In reality, suture designers do not sterilize suture designs to prove the concept unless the designs have something particular to do with sterilization. Here, the focus was on suture properties, and biological testing was not needed.

179. My opinion is supported by Mr. Grafton's deposition testimony concerning the development of the FiberWire product. Mr. Grafton testified that, after Arthrex tested the prototype suture braid of UHMW PE and PET, Arthrex believed it would work as a suture (Ex. 12 at 57). Although Mr. Grafton was not sure whether the sutures he tested were sterile or nonsterile (and I know of nothing indicating they were sterile), Mr. Grafton testified that sterilization would not be necessary at this stage of development, because it was only the mechanical features of the suture being tested, not the bio-burden levels (Ex. 12 at 60). Thus, Mr. Grafton's testimony supports my opinion that sterilization is typically not needed to prove the mechanical properties of a braided suture.

180. Dr. Mukherjee's testimony is contradicted by Arthrex's and Pearsall's own practices. I understand that Arthrex tested unsterile sutures when it tested coated and uncoated samples to show that FiberWire's coating has an effect on FiberWire's lubricity (Ex. 12 at 149). Arthrex's engineer who coordinated that testing was aware of the known sterilization techniques (Ex. 12 at 97). He must not have thought that sterilization could have a "substantial effect" on the braid properties, as suggested by Dr. Mukherjee, because otherwise he would have tested sterile sutures. If sterilization could have a "substantial effect" on the braid properties as Dr. Mukherjee suggests, then this casts doubt on the reliability of Arthrex's test results. Also, Pearsalls issued certificates of conformity on the braids that they made for Arthrex's FiberWire that describe certain suture properties such as knot strength. Arthrex has submitted these documents to the FDA. But Pearsalls does not sterilize sutures.

181. Dr. Mukherjee also opines that the 446 invention was not actually reduced to practice because there were “technical problems with the invention” (Mukherjee at 28-30). Dr. Mukherjee describes these problems as “core popping and braid looseness” (Mukherjee at 28). I disagree.

182. I first note that Dr. Mukherjee appears to take Dr. Steckel’s “braid looseness” and “core popping” comments out of context. For example, Dr. Steckel testified that the CBE-15 suture braid has been made on June 6, 1988, and there is no core popping or braid looseness documented with respect to that construction. Rather, the only documented braid construction “issues” with respect to the June prototypes involved yarn blended prototypes, not the carrier blended prototypes, such as CBE-0015 (Ex. 26 at DMI02620). Further, there is no documented “core popping” or “braid looseness” with respect to the braids constructed and tested in December 1989. Thus, contrary to Dr. Mukherjee’s suggestions Dr. Steckel had constructed PET/PTFE braids that did not have any “core popping” or “braid looseness” that was significant enough to document. Although Dr. Steckel did comment that the sutures evaluated in February 1989 had some “core popping” and “braid looseness,” these were “infrequent” issues (Ex. 25 at 227-229). Most significantly, they did not prevent Dr. Steckel from constructing and evaluating the braids (Ex. 25 at 227-229). Anyway, only part of the braid that he constructed had core popping or braid looseness. Thus, the part that did not coupled with the other prototypes was more than sufficient to show that his sutures would work for their intended purpose. As Dr. Steckel stated, although certain prototypes had core popping and braid looseness, these issues did not prevent him from making and evaluating the suture and its properties (Ex. 25 at 228). For example, he did not have to

make 100 meters of perfect suture to prove that the suture would work for its intended purpose. It was more than sufficient to have some portion of the 100 meters that did not have core popping and braid looseness to show that he had built a suture that could work for its intended purpose (Ex. 25 at 229-230). For example, Dr. Steckel concluded that the December 1989 prototypes had “exceptional handling properties” (Ex. 26 at DMI002665). If core popping and braid looseness was as big a problem as Dr. Mukherjee suggests, then Dr. Steckel could not have made this conclusion.

183. I also disagree with Dr. Mukherjee’s opinions that any “braid looseness” and “core popping” that the inventors experienced prevented them from making a product that would work for its intended purpose because these are really manufacturing/commercialization concerns, not proof of concept issues. “Core popping” and “braid looseness” are routine manufacturing details that are typically encountered when developing prototypes or even commercial products (Ex. 25 at 227). As Dr. Steckel testified, core popping and braid looseness are inherent in any braiding manufacturing process and quality control steps are used to eliminate any defective material when making commercial products (Ex. 25 at 227-231). “Core popping” and “braid looseness” are the type of details that are minimized when making a commercial product, so as to maximize the amount of manufactured suture that is suitable for a commercial product. My opinion is supported by the testimony of Brian Hallet of Pearsalls. As Mr. Hallet stated, core popping is a minor issue that generally arises in manufacturing braids (Ex. 23 at 192-193).

184. I also note that Dr. Mukherjee refers to a February 1990 memorandum discussing so-called “technical problems” (Mukherjee at 30). Based on all the testimony

and Dr. Steckel's notebook, I believe that he takes this memorandum out of context because it dealt with the issue of whether to pursue Dr. Steckel's concept further for certain purposes, not whether he had shown that the concept would work as a suture (Ex. 25 at 249-252). Also, I note that Dr. Mukherjee's processing "problems" discussion ignores the examples provided in the 446 patent (Ex. 2 at 7:36-63). These additional examples further show that the invention had been reduced to practice.

IX. Mr. Goodwin's Statement While Prosecuting the 446 Patent Was Not Inconsistent With Dr. Steckel's Testimony

185. I have read Mr. Witherspoon's report and, in particular, paragraphs 58-63 in which he suggests that Mr. Goodwin, one of the attorneys who prosecuted the 446 Patent, made an argument that was materially inconsistent with the testimony of Dr. Steckel. I have reviewed the arguments before the Examiner, the Burgess reference, and Dr. Steckel's testimony, and I do not agree for several reasons. First, Mr. Witherspoon misstates Mr. Goodwin's statement to the Examiner. Second, it is not clear what statements he is referring to from Dr. Steckel because he provides no citation. Third, Dr. Steckel's testimony is not inconsistent with Mr. Goodwin's statements, let alone materially inconsistent. Fourth, in any event, nothing was withheld from the Examiner because the application for the 446 patent discloses ultra high molecular weight polyethylene, UHMW PE.

186. I disagree with Mr. Witherspoon because he attributes a statement to Mr. Goodwin that he did not make. Mr. Witherspoon states that Mr. Goodwin represented to the Examiner that "if a medical designer were to actually build a suture using the braided combination of UHMW PE and polyester, then 'he would inevitably design an unacceptable suture'" (Witherspoon at ¶61). This is not what Mr. Goodwin said. Mr.

Goodwin said if a suture designer uses “*the teachings of the fishing line art* to modify a suture, then one would inevitably design an unacceptable suture” (Ex. 17 at DMI000608-609) (emphasis added). Thus, I disagree with Mr. Witherspoon because his opinion is factually incorrect; it is based on a statement that Mr. Goodwin did not make.

187. Even assuming that Mr. Witherspoon was referring to Mr. Goodwin’s statement – if a medical designer uses “the *teachings* of the fishing line art to modify a suture, then one would inevitably design an unacceptable suture” -- I still disagree with Mr. Witherspoon. Mr. Goodwin’s statement is a correct statement and there is nothing misleading about it. Burgess discusses a fishing line that is “non-stretchable” (Ex. 7 at 1). As Mr. Goodwin explained to the Examiner, those skilled in the art of developing surgical sutures would have known that it is important for a suture to have some stretchability for forming good knots. Further, as Mr. Goodwin also explained (Ex. 17 at DMI000607), Burgess does not mention knot security or knot strength or how the braid should be constructed to achieve them. Thus, if a suture designer followed Burgess’ teachings about how to make a fishing line, one would be focusing on designing an acceptable fishing line, but not an acceptable suture.

188. I also disagree with Mr. Witherspoon because he does not specifically state what it is Dr. Steckel said that was inconsistent with Mr. Goodwin’s statements (Witherspoon at ¶62). Mr. Witherspoon's report does not quote or cite to any specific testimony from Dr. Steckel. Rather, Mr. Witherspoon generally characterizes Dr. Steckel’s testimony. Since he has not specifically identified Dr. Steckel’s statement, it is difficult to address his opinions.

189. Nevertheless, even if Dr. Steckel said what Mr. Witherspoon believes he said, Dr. Steckel's testimony is not inconsistent with what Mr. Goodwin wrote to the Examiner. Mr. Goodwin's statement was directed to what a suture designer would do based on the teachings of Burgess, a fishing line reference. In contrast, Dr. Steckel's testimony was directed to his idea, not the teachings of a fishing line reference, and not how a suture designer would react based on Burgess. In fact, Dr. Steckel never testified about the substantive teachings of a fishing line reference nor the substantive teachings of Burgess, nor what would happen if a medical designer followed the teachings of a fishing line reference or Burgess. Thus, the statements are not inconsistent, let alone materially inconsistent.

190. I also disagree with Mr. Witherspoon's opinion because it appears to be based on the notion that Dr. Steckel and Mr. Goodwin did not inform the Patent Office that braiding UHMW PE and polyester would lead to an acceptable suture. But Dr. Steckel did describe his invention as including a braid of UHMW PE and PET (which is a polyester) in his patent application. Therefore, Dr. Steckel's testimony, that was allegedly not disclosed, was in-fact disclosed.

191. Not only were the statements consistent with Dr. Steckel's testimony, but they are true and, indeed, are supported by testimony of Arthrex's own witnesses. I understand that Arthrex witness, Don Grafton, testified at his deposition that knot tie down, which he defined as related to knot strength, would be poor with a UHMWPE suture (Ex. 12 at 26:14-31:1; 52-53). I also note that this is confirmed in the 234 patent application filed by Arthrex. Arthrex's 234 patent states that "[o]ne of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain

polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema and Spectra. However, this material, while stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical application” (Ex. 14 at 1:13-21). These statements appear to be consistent with Mr. Goodwin’s statements to the Patent Office regarding the Burgess fishing line and contradict Dr. Witherspoon’s opinion that there was something misleading about Mr. Goodwin’s statements.

192. If necessary to further rebut any arguments made regarding Burgess, I may testify about the prosecution history of the 446 patent as it would be understood by a person of ordinary skill in the art. As explained above, the Examiner had rejected pending claims 21-24 as obvious over Burgess. The Examiner never stated what “braided construction” Burgess taught or that Burgess disclosed “direct intertwining contact.” In responding to this office action, Mr. Goodwin argued that it would have been non-obvious based on differences between Burgess and the claims and fishing line and suture.

193. Mr. Goodwin explained that sutures must have good knot strength and knot security. This is accurate. He also explained that for fishing line knot security and knot strength are “not as critical” because they do not “keep a stitched wound intact” (Ex. 17 at DMI000607). Again, this is accurate and supported by the fact that Burgess does not discuss either knot strength or knot security.

194. The main focus of Mr. Goodwin’s response was that since Burgess describes fishing line design criteria that are different from suture design criteria, one of ordinary skill in the art would not look to Burgess. But even if a medical designer did consider

Burgess, Burgess does not disclose any particular braid, and he would be led down a path of designing a suture to achieve the fishing line properties disclosed in Burgess, not a suture that maximizes suture properties. Burgess says nothing about how to make a braid to achieve knot security or knot strength.

195. At trial, I may use demonstrative exhibits that I have not yet created to further explain my opinions.

Dated: March 24, 2006

A handwritten signature in black ink, appearing to read "M. E. Hermes", written over a horizontal line.

Matthew Hermes Ph.D.

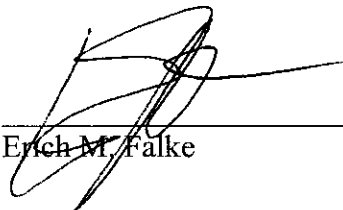
CERTIFICATE OF SERVICE

I certify that the foregoing Expert Report of Dr. Matthew Hermes was served by e-mail without exhibits and Federal Express overnight mail (Saturday delivery) with exhibits on March 24, 2006 on the following:

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Dated: March 24, 2006



Erich M. Falke

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a)
Massachusetts corporation,)
Plaintiff,) Civil Action
vs.) 04-12457 PBS
ARTHREX, INC., a Delaware)
corporation,)
Defendant.)

- - - - -
The deposition of DEBI PRASAD
MUKHERJEE was taken on Tuesday, June 13,
2006, commencing at 9:08 a.m., at the
offices of Dickstein Shapiro Morin &
Oshinsky LLP, 2101 L Street, N.W.,
Washington, D.C., before Susanne Bergling,
Registered Merit Reporter and Notary Public.

<p>1 with respect --</p> <p>2 A. Yes.</p> <p>3 Q. And they have not communicated to you why</p> <p>4 you have not made full professor?</p> <p>5 A. They did, but there is no specific reason</p> <p>6 even.</p> <p>7 Q. Well, what did they communicate to you?</p> <p>8 A. That at this point in time, the committee</p> <p>9 felt that the promotion didn't go through.</p> <p>10 Q. Okay. And how many times has the promotion</p> <p>11 to full professorship not gone through?</p> <p>12 A. Just once.</p> <p>13 Q. Just once. When was that?</p> <p>14 A. I don't remember, two-three years ago.</p> <p>15 Q. Excuse me?</p> <p>16 A. About two-three years ago.</p> <p>17 Q. Okay. And so you don't know why the</p> <p>18 professor -- the full professorship didn't go</p> <p>19 through?</p> <p>20 MR. TAMBURO: Objection, asked and</p> <p>21 answered.</p> <p>22 THE WITNESS: No, I don't.</p> <p>23 BY MR. BONELLA:</p> <p>24 Q. And they didn't tell you the things that</p> <p>25 you could do to make full professor?</p>	<p>18 1 '92?</p> <p>2 A. Yes.</p> <p>3 Q. What type of biomaterials did you develop</p> <p>4 at Union Carbide?</p> <p>5 A. Some biomaterials for ophthalmic</p> <p>6 application, ophthalmic surgery applications.</p> <p>7 Q. Can you explain the materials?</p> <p>8 A. I cannot go too far into this.</p> <p>9 Q. It's confidential?</p> <p>10 A. Yes.</p> <p>11 Q. Can you generally describe what the</p> <p>12 materials you developed were?</p> <p>13 A. They are natural materials coming out of</p> <p>14 polysaccharide complex.</p> <p>15 Q. So, the materials you developed at Union</p> <p>16 Carbide were bioabsorbable materials. Is that</p> <p>17 true?</p> <p>18 A. Some bioabsorbable, some nonbioabsorbable.</p> <p>19 Q. Okay. Did you develop applications for the</p> <p>20 materials that you developed at Union Carbide?</p> <p>21 A. Yes, that's the purpose.</p> <p>22 Q. And what were the applications for the</p> <p>23 materials you developed at Union Carbide?</p> <p>24 A. For ophthalmic surgery use.</p> <p>25 Q. How were -- how were they to be used in</p>
<p>19 1 A. No.</p> <p>2 Q. Have your job responsibilities at Louisiana</p> <p>3 State University pretty much stayed the same since</p> <p>4 1992?</p> <p>5 A. Yes.</p> <p>6 Q. In 1991 to 1992 -- let me back up, one more</p> <p>7 question.</p> <p>8 Do you have tenure at Louisiana State</p> <p>9 University?</p> <p>10 A. Yes.</p> <p>11 Q. And what do you mean by that?</p> <p>12 A. What is meant by tenure.</p> <p>13 Q. Right. What do you mean -- what's your --</p> <p>14 what do you mean by tenure?</p> <p>15 A. As I understood it, lifetime employment.</p> <p>16 Q. Okay. Before you were at LSU, you were a</p> <p>17 developmental scientist for Union Carbide. Is</p> <p>18 that right?</p> <p>19 A. Yes.</p> <p>20 Q. And what were your job responsibilities at</p> <p>21 Union Carbide?</p> <p>22 A. Developing biomaterials.</p> <p>23 Q. Developing biomaterials?</p> <p>24 A. (Witness nods head.)</p> <p>25 Q. And you were at Union Carbide from '91 to</p>	<p>21 1 ophthalmic surgery?</p> <p>2 A. There was a material of hyaluronic acid</p> <p>3 used for viscosurgery, for viscosupplementation.</p> <p>4 Q. What type of surgery?</p> <p>5 A. For cataract surgery.</p> <p>6 Q. Cataract surgery. I didn't understand the</p> <p>7 word you said. You said viscal?</p> <p>8 A. Viscosupplementation.</p> <p>9 Q. V I S C?</p> <p>10 A. O, supplementation.</p> <p>11 Q. And what is that?</p> <p>12 A. That protects the eyes -- the cells in the</p> <p>13 eyes so it doesn't degrade when the surgery is</p> <p>14 done.</p> <p>15 Q. And how is the -- how is the material that</p> <p>16 you developed at Union Carbide intended to be used</p> <p>17 in this type of surgery?</p> <p>18 A. We were working on the replacement of</p> <p>19 hyaluronic acid by a natural material.</p> <p>20 Q. So, the material you developed for Union</p> <p>21 Carbide wasn't for a suture?</p> <p>22 A. No.</p> <p>23 Q. Did you do any work with respect to sutures</p> <p>24 at Union Carbide?</p> <p>25 A. No.</p>

6 (Pages 18 to 21)

<p style="text-align: right;">22</p> <p>1 Q. Okay. Before you were at Union Carbide, 2 you were a research program manager for Dow 3 Corning Wright? 4 A. Yes. 5 Q. And you were at Dow Corning Wright from '87 6 to '90? 7 A. Yes. 8 Q. What were your job responsibilities as 9 research program manager at Dow Corning Wright? 10 A. Composite materials development for 11 orthopedic application. 12 THE REPORTER: I'm sorry, can you repeat 13 that? 14 THE WITNESS: Composite materials 15 development for orthopedic application. 16 BY MR. BONELLA: 17 Q. What type of materials did you develop at 18 Dow Corning Wright? 19 A. I didn't develop. I was bringing the 20 technology from outside. 21 Q. What do you mean by you were bringing 22 technology from outside while you were at Dow 23 Corning Wright? 24 A. There was a licensed technology coming out 25 of France, and I worked as a program manager on</p>	<p style="text-align: right;">24</p> <p>1 Q. Was the material that you were working on 2 at Dow Corning Wright, was that for suture 3 applications? 4 A. No, for a lot of different applications, 5 for ligaments to hernia repair, all the other 6 things. 7 Q. So, the suture you were -- or I'm sorry, 8 the material you were working on at Dow Corning 9 Wright was for ligament applications? 10 A. That was used at one time. 11 Q. It was used? 12 A. Not here, but in France. 13 Q. Did you ever consider using the material 14 that you were working on at Dow Corning Wright for 15 suture applications? 16 A. We -- we thought about it, but we didn't do 17 anything. 18 Q. Okay. And what do you mean by the material 19 you were working on at Dow Corning Wright had 20 ligament applications? 21 A. Because carbon fiber has been used for 22 ligaments before. So, we were using the exist 23 technology or some other that can be used for 24 ligaments. 25 Q. Did you actually develop a product that --</p>
<p style="text-align: right;">23</p> <p>1 that project. 2 Q. So, Dow Corning Wright was licensing 3 technology from somewhere, France? 4 A. From some company in France. 5 Q. And you were working on the -- on the 6 material that would have been licensed? 7 A. Yes. 8 Q. What material was that? 9 A. These are proprietary materials. 10 Q. Okay. Can you generally describe it? 11 A. I can -- I can go into general. 12 Q. Can you generally describe the material? 13 A. It's a carbon composite. 14 Q. Carbon composite. 15 Is it fair to say while you were at Dow 16 Corning Wright, you didn't -- you didn't do any 17 work on sutures? 18 A. Well, from time to time, because of my 19 expertise in sutures, the other groups asked for 20 my opinion, but there are several different 21 things. 22 Q. Okay. Is it fair to say in your day-to-day 23 activities while you were at Dow Corning Wright, 24 your projects generally did not involve sutures? 25 A. That's correct.</p>	<p style="text-align: right;">25</p> <p>1 a ligament type product for Dow Corning Wright? 2 A. No. 3 Q. No. What -- can you describe more 4 specifically what your responsibilities were with 5 respect to this material while you were at Dow 6 Corning Wright? 7 A. I made sure that the -- they were properly 8 made, meaning the specs are maintained 9 material-wise; tested the -- the implant that we 10 were developing; and coordinated the entire 11 activities so that the product would be 12 commercialized. 13 Q. But the product was never commercialized? 14 A. No. 15 Q. Why is that? 16 A. It has several reasons. It didn't meet the 17 specs. 18 Q. It didn't meet the specs? 19 A. Or application. 20 Q. And what specs were you trying to meet? 21 A. There are many of them. I cannot go in 22 details. 23 Q. You can't? Why not? 24 A. A lot of these are proprietary information. 25 Q. Okay. When you say they weren't properly</p>

<p style="text-align: right;">70</p> <p>1 You just have to say you don't remember.</p> <p>2 A. Yeah, I say I don't remember.</p> <p>3 Q. Do you remember if you were trying to take</p> <p>4 the Hytrel/Maxon sutures and try to change their</p> <p>5 elasticity properties to match the ACL when you</p> <p>6 were developing the ligaments?</p> <p>7 A. We did both, construction-wise, braid-wise,</p> <p>8 and most of the time, if I remember correctly,</p> <p>9 that the fibers that we made, they have the same</p> <p>10 properties as the suture.</p> <p>11 Q. Do you remember any specific property</p> <p>12 testing that you did to support that statement?</p> <p>13 A. Many of them. I don't remember specifics.</p> <p>14 Q. Okay. Tell me -- tell me what you remember</p> <p>15 as the measurement of the elasticity of the</p> <p>16 sutures to be relative to the ligaments that you</p> <p>17 developed.</p> <p>18 MR. TAMBURIO: Objection, he just said he</p> <p>19 doesn't remember the specifics.</p> <p>20 THE WITNESS: I don't remember specifics,</p> <p>21 but the general testing, general mechanical</p> <p>22 testing in doing sutures.</p> <p>23 BY MR. BONELLA:</p> <p>24 Q. Do you remember any values, any numbers?</p> <p>25 A. No, I don't.</p>	<p style="text-align: right;">72</p> <p>1 ligatures or for ligaments in the knee, right?</p> <p>2 MR. TAMBURIO: Objection, asked and</p> <p>3 answered, and it mischaracterizes testimony.</p> <p>4 THE WITNESS: Again, I don't remember.</p> <p>5 BY MR. BONELLA:</p> <p>6 Q. Now, before you were at Davis & Geck, you</p> <p>7 were a senior research engineer at Goodyear Tire &</p> <p>8 Rubber Company?</p> <p>9 A. Yes.</p> <p>10 Q. What work did you do at Goodyear Tire &</p> <p>11 Rubber Company?</p> <p>12 A. We were developing materials for Hart (ph)</p> <p>13 out of Chicago at that time, but that was my --</p> <p>14 part of the work. The other main work was a</p> <p>15 characterization of rubbers and materials used in</p> <p>16 tires.</p> <p>17 Q. No suture work while you were at Goodyear</p> <p>18 Tire & Rubber Company?</p> <p>19 A. No.</p> <p>20 Q. "No" meaning you didn't do any suture work</p> <p>21 at the Goodyear Tire & Rubber Company, correct?</p> <p>22 A. Say that again.</p> <p>23 Q. When you said -- I said no in my question,</p> <p>24 you said no in your answer, so I wasn't sure if it</p> <p>25 was clear, so I just wanted to rephrase it to make</p>
<p style="text-align: right;">71</p> <p>1 Q. Do you have any documentation of the</p> <p>2 elasticity properties?</p> <p>3 MR. TAMBURIO: From 30 years ago?</p> <p>4 MR. BONELLA: Yeah.</p> <p>5 BY MR. BONELLA:</p> <p>6 Q. Do you have anything to support your</p> <p>7 statement that you just made?</p> <p>8 A. No, I don't have any.</p> <p>9 Q. Okay. Do you remember any other properties</p> <p>10 that had to be changed with respect to the Hytrel</p> <p>11 and Maxon sutures to make them into ligaments?</p> <p>12 A. Again, I don't remember specifics. I'm</p> <p>13 sure there were.</p> <p>14 Q. Now, to make them into ligaments, what work</p> <p>15 had to be done? You said braiding, right?</p> <p>16 A. Again, these are 30 years ago. I don't</p> <p>17 know all the details. There are many, though.</p> <p>18 Q. What had to be changed about the braiding,</p> <p>19 do you remember?</p> <p>20 A. No, I don't.</p> <p>21 Q. Okay. Do you remember the diameter size of</p> <p>22 the ACL ligament you were trying to replace?</p> <p>23 A. I don't remember.</p> <p>24 Q. It wasn't the case that you would just take</p> <p>25 the Hytrel and Maxon sutures and use them as</p>	<p style="text-align: right;">73</p> <p>1 it clear.</p> <p>2 It's true that you did not do any suture</p> <p>3 work at the Goodyear Tire & Rubber Company,</p> <p>4 correct?</p> <p>5 A. That's correct.</p> <p>6 Q. And you didn't do any ligature work while</p> <p>7 you were at the Goodyear Tire & Rubber Company,</p> <p>8 correct?</p> <p>9 A. No, I didn't work in -- did not.</p> <p>10 Q. You did not do ligature work while you were</p> <p>11 at the Goodyear Tire & Rubber Company, right?</p> <p>12 A. Correct.</p> <p>13 Q. What's a ligature versus a suture?</p> <p>14 A. Are you asking me?</p> <p>15 Q. Yeah.</p> <p>16 A. A ligature -- I mean, again, in a very</p> <p>17 simple way, not a surgical definition, an entire</p> <p>18 vessel, it could be a single strand fiber, it</p> <p>19 could be just like a suture, you can use as a</p> <p>20 ligature.</p> <p>21 Q. What's the difference between a ligature</p> <p>22 and a suture? I don't understand what you said.</p> <p>23 Is --</p> <p>24 A. You can -- suture, as we know, that could</p> <p>25 be single strand, multistrand, needle, non-needle,</p>

<p>118</p> <p>1 Q. Oh, so you were hired by the law firm?</p> <p>2 A. Not hired, but --</p> <p>3 Q. Are you --</p> <p>4 A. -- I'm paid per hour for a consulting fee</p> <p>5 as an expert.</p> <p>6 Q. Are you paid by the law firm or are you</p> <p>7 paid by Arthrex and Pearsalls?</p> <p>8 A. I'm not sure who pay, but I send it to the</p> <p>9 law firm.</p> <p>10 Q. Have you ever done any work for a J&J</p> <p>11 company?</p> <p>12 A. No.</p> <p>13 Q. Are you familiar with Ethicon?</p> <p>14 A. Very much.</p> <p>15 Q. Have you ever done any work for Ethicon?</p> <p>16 A. No, I didn't.</p> <p>17 Q. How about DePuy Mitek, have you ever done</p> <p>18 any work for them?</p> <p>19 A. No.</p> <p>20 Q. Okay. Ever do any work for U.S. Surgical?</p> <p>21 A. No.</p> <p>22 Q. Okay. You're being paid a thousand dollars</p> <p>23 a day for this case?</p> <p>24 A. That's correct.</p> <p>25 Q. Okay. So, what happens when you only put</p>	<p>120</p> <p>1 working as an independent expert.</p> <p>2 Q. Okay. And how much --</p> <p>3 I think we need a break for the tape.</p> <p>4 VIDEOGRAPHER: This ends videotape number</p> <p>5 one. We're going off the record at 11:18.</p> <p>6 (A brief recess was taken.)</p> <p>7 VIDEOGRAPHER: This begins videotape number</p> <p>8 two. We're back on the record at 11:20.</p> <p>9 BY MR. BONELLA:</p> <p>10 Q. Have you ever been to Pearsalls?</p> <p>11 A. No.</p> <p>12 Q. So, you have not inspected their</p> <p>13 manufacturing facilities?</p> <p>14 A. No.</p> <p>15 Q. Did you ever speak with anyone from</p> <p>16 Pearsalls?</p> <p>17 A. No.</p> <p>18 Q. Have you spoke with a Brian Benavitz from</p> <p>19 Arthrex regarding this case?</p> <p>20 MR. TAMBURRO: Objection. Bill Benavitz?</p> <p>21 MR. BONELLA: I'm sorry, Bill Benavitz.</p> <p>22 THE WITNESS: Yes, I spoke to him.</p> <p>23 BY MR. BONELLA:</p> <p>24 Q. Okay. Anybody else from Arthrex you spoke</p> <p>25 to regarding this case?</p>
<p>119</p> <p>1 in an hour a day?</p> <p>2 A. Then I charge like \$150 an hour.</p> <p>3 Q. Okay. And when do you charge the full rate</p> <p>4 of a thousand dollars a day, how many hours do you</p> <p>5 have to put in?</p> <p>6 A. I -- I am on the old standard, eight hours</p> <p>7 a day.</p> <p>8 Q. So, when you put eight hours a day in for</p> <p>9 this case, you a charge a thousand?</p> <p>10 A. That's correct.</p> <p>11 Q. And if it's less than eight, charge 150 an</p> <p>12 hour?</p> <p>13 A. Well, if it's whole day, if it's six and a</p> <p>14 half or seven, I don't cut it that close, but</p> <p>15 usually one day is eight hours, but I only divide</p> <p>16 by hours for a day. If I use one day, like this</p> <p>17 here, it will be a thousand dollars a day.</p> <p>18 Q. Okay. If you work less than eight hours a</p> <p>19 day on this case, what do you charge?</p> <p>20 A. I do -- pro rate it based on hours I spent.</p> <p>21 Q. Okay. And do you know --</p> <p>22 A. But I'm an independent expert, not hired by</p> <p>23 anybody except by this -- this consulting fee.</p> <p>24 Q. Right, you were hired by the law firm.</p> <p>25 A. Well, they contacted me. Again, I am</p>	<p>121</p> <p>1 A. No.</p> <p>2 Q. Anyone else besides the lawyers that you've</p> <p>3 spoken to regarding this case?</p> <p>4 MR. TAMBURRO: Objection. You mean with</p> <p>5 Arthrex or anybody at all?</p> <p>6 MR. BONELLA: I'm sorry, I'll rephrase the</p> <p>7 question.</p> <p>8 BY MR. BONELLA:</p> <p>9 Q. Anybody besides Mr. Benavitz and the --</p> <p>10 Mr. Tamburo's law firm, besides those people, have</p> <p>11 you spoken with anyone else regarding this case?</p> <p>12 A. No.</p> <p>13 Q. Okay. How about Dr. Gitis, have you ever</p> <p>14 spoken with him?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. How about Dr. Burks, have you ever</p> <p>17 spoken with him?</p> <p>18 A. No.</p> <p>19 Q. Okay. You have spoken with Dr. Gitis. How</p> <p>20 many times have you spoken with Dr. Gitis?</p> <p>21 A. Several times.</p> <p>22 Q. Several times, okay.</p> <p>23 You say you never spoke with an Ashley</p> <p>24 Holloway?</p> <p>25 A. No.</p>

<p style="text-align: right;">382</p> <p>1 how the samples should be made?</p> <p>2 A. No.</p> <p>3 Q. Okay. What do you know about --</p> <p>4 A. Except -- huh?</p> <p>5 Q. Oh, sorry, go ahead.</p> <p>6 A. Except one batch was coated, other batch</p> <p>7 was uncoated, that's all.</p> <p>8 Q. What was -- was that your -- so, did you</p> <p>9 contribute to that, saying one batch should be</p> <p>10 coated, one batch should be uncoated?</p> <p>11 A. I mentioned to our attorneys and also Norm</p> <p>12 Gitis.</p> <p>13 Q. Okay. Did you contribute anything else</p> <p>14 about how the sutures should be made, the coated</p> <p>15 and uncoated samples that Dr. Gitis tested?</p> <p>16 A. No.</p> <p>17 Q. No?</p> <p>18 A. No.</p> <p>19 Q. Okay. Did you analyze any of the processes</p> <p>20 that Pearsalls used to make sutures in determining</p> <p>21 what the samples should be?</p> <p>22 A. No.</p> <p>23 Q. Okay. Are you familiar with any of the</p> <p>24 specific processes that Pearsalls used to</p> <p>25 manufacture sutures?</p>	<p style="text-align: right;">384</p> <p>1 Q. Do you know what procedure he used?</p> <p>2 A. It's in the figure 1, test setup for</p> <p>3 pliability testing.</p> <p>4 Q. Okay. He used a test for pliability</p> <p>5 testing, right?</p> <p>6 A. Yeah.</p> <p>7 Q. That's based on the relationship of K</p> <p>8 equals $E \cdot I$?</p> <p>9 A. Yes.</p> <p>10 Q. Where K is stiffness, E is modulus of</p> <p>11 elasticity and I is moment of inertia, right?</p> <p>12 A. Yes.</p> <p>13 Q. Isn't that test for monofilament sutures?</p> <p>14 A. You -- you can do it, we have done in the</p> <p>15 past, not his setup, but we have done in the past</p> <p>16 when I was at Davis & Geck.</p> <p>17 Q. I don't understand your answer.</p> <p>18 A. So, not necessarily monofilament. You can</p> <p>19 do very easily the coated suture. Uncoated you</p> <p>20 can do that, too.</p> <p>21 Q. Doesn't this test that he did with the K</p> <p>22 equals $E \cdot I$ analysis assume a monofilament</p> <p>23 structure?</p> <p>24 A. No.</p> <p>25 Q. It doesn't?</p>
<p style="text-align: right;">383</p> <p>1 A. No.</p> <p>2 Q. Okay. Now, I'd like to turn to Dr. Gitis'</p> <p>3 testing, please. That's Exhibit 20 to your</p> <p>4 responsive report.</p> <p>5 A. Which one is that?</p> <p>6 MR. TAMBURRO: 240.</p> <p>7 THE WITNESS: 240. Yeah. Exhibit --</p> <p>8 MR. TAMBURRO: Exhibit 20.</p> <p>9 THE WITNESS: Twenty, okay.</p> <p>10 BY MR. BONELLA:</p> <p>11 Q. Okay, do you see on page 2 of his report,</p> <p>12 it refers to pliability tests at the bottom?</p> <p>13 A. Yeah.</p> <p>14 Q. Okay. And are you familiar with the</p> <p>15 pliability tests that he did?</p> <p>16 A. Vaguely, because he's expert. He decided</p> <p>17 what tests to be done. We need this kind of data.</p> <p>18 So, he said we need this. So, that's the</p> <p>19 discussion I had with -- I had with him several</p> <p>20 times, but the actual procedure, he's the expert.</p> <p>21 Q. He's the expert on that?</p> <p>22 A. Yeah.</p> <p>23 Q. Okay. Do you know what procedure he used?</p> <p>24 A. It's in the drawing there, but I haven't --</p> <p>25 you know, myself, I didn't do it.</p>	<p style="text-align: right;">385</p> <p>1 A. No, it doesn't.</p> <p>2 Q. How does it account for variations in</p> <p>3 filaments?</p> <p>4 A. He does not. He just measures the modulus</p> <p>5 of elasticity by bending, and then the --</p> <p>6 calculate from the dimensions the I, and then get</p> <p>7 the K.</p> <p>8 Q. So, it assumes that you have a constant</p> <p>9 cross-section, doesn't it?</p> <p>10 MR. TAMBURRO: Objection, the witness</p> <p>11 already said he's not an expert on how the test</p> <p>12 was done.</p> <p>13 THE WITNESS: It has been used, but there</p> <p>14 are errors in there, but it has been used --</p> <p>15 BY MR. BONELLA:</p> <p>16 Q. It didn't say it wasn't --</p> <p>17 A. -- with braided sutures also.</p> <p>18 Q. I didn't say whether it had been used or</p> <p>19 not used. My question is, doesn't it assume a</p> <p>20 monofilament structure?</p> <p>21 A. No.</p> <p>22 Q. It doesn't?</p> <p>23 A. No.</p> <p>24 Q. How does it -- doesn't it assume a</p> <p>25 diameter, a constant diameter, the way it was</p>

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3 Civil Action No. 04-12457 PBS

4
5 DEPUY MITEK, INC., a Massachusetts)

6 Corporation,)

7 Plaintiff,)

8 v.)

9 ARTHREX, INC., a Delaware Corporation)

10 Defendant.)

11
12
13
14 Videotaped Deposition of DEBI PRASAD MUKHERJEE

15 - VOLUME TWO -

16 Washington, DC

17 Wednesday, June 14, 2006

18
19 The videotaped deposition of DEBI PRASAD MUKHERJEE,

20 Volume Two, was held on Wednesday, June 14, 2006,

21 commencing at 9:12 a.m., at the offices of Dickstein

22 Shapiro Morin & Oshinsky LLP, 2101 L Street,

23 Northwest, Washington, DC, before Mary Ann Payonk,

24 RDR, Certified Realtime Reporter, Registered Diplomate

25 Reporter and Notary Public.

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<p style="text-align: right;">502</p> <p>1 used gloves or didn't use gloves. And surgeons 2 normally use gloves. 3 MR. TAMBURIO: Objection. That assumes 4 facts not in -- I haven't heard a question yet. 5 BY MR. BONELLA: 6 Q Right? So my question was -- 7 A Yes. 8 Q -- he did a tactile feel analysis. Do you 9 see that? And he said the difference between -- and 10 he said there's a difference between the samples 11 suture A and suture B when he did the tactile feel 12 analysis, right? 13 A That's correct. 14 Q My question to you is: Should he have 15 done that tactile feel analysis with gloves on or with 16 gloves off to determine the difference? 17 MR. TAMBURIO: Objection. Same objection. 18 The witness is not qualified to answer whether or not 19 a surgeon should conduct his tactile feel with gloves 20 or no gloves. The surgeon is the only person that's 21 qualified to answer that question. 22 A I cannot answer that. Dr. Burks is the 23 person, expert can answer that question. 24 BY MR. BONELLA: 25 Q Would it matter to your analysis or your</p>	<p style="text-align: right;">504</p> <p>1 A Yes. 2 Q And what opinions can you reach? 3 A According to him, the suture A, which is 4 the coated, felt smoother than the suture B, was 5 uncoated. 6 Q Well, if he had done that test and -- with 7 gloves on and couldn't tell which was smoother, then 8 had to take the gloves off to figure out which one was 9 smoother, would that affect your analysis? 10 A Again, that's a hypothetical question. 11 That did not happen, so I have no opinion on that. 12 Q Well, if it did happen, would that change 13 your opinion? 14 A I -- I will not guess so I don't have any 15 opinion on that. 16 Q You have no opinion on that? 17 A That's correct. 18 Q How about for the knot tiedown analysis 19 that he talks about in paragraph 12? If Dr. Burks 20 couldn't tell any significant difference between 21 suture A and suture B when doing the knot tiedown 22 analysis in paragraph 12 when he had gloves on, would 23 that change your analysis? 24 MR. TAMBURIO: Objection, vague. 25 A Again, this is a hypothetical question,</p>
<p style="text-align: right;">503</p> <p>1 opinions if -- if the tactile feel analysis that he 2 conducted, he couldn't tell any significant difference 3 between suture A and suture B when he had gloves on? 4 MR. TAMBURIO: Objection, vague. 5 A Same answer as before. 6 BY MR. BONELLA: 7 Q What? 8 A I cannot. 9 Q You cannot answer it? 10 A I don't have any opinion. 11 Q You have no opinion? 12 A That's correct. 13 Q Why not? 14 A I explained to you that Dr. Burks is the 15 expert. And I'm not an MD, so I can't explain that. 16 Q Can you reach any conclusions about the 17 effects of coating on FiberWire based on Dr. Burks' 18 analysis? 19 A Would you please repeat? 20 Q Sure. Could you reach any opinions based 21 on -- I'm sorry. Can you reach any opinions based -- 22 I'm sorry. 23 Can you reach any opinions about the 24 effects of coating on FiberWire based on Dr. Burks' 25 testing?</p>	<p style="text-align: right;">505</p> <p>1 and Dr. Burks is the expert. And I have no opinion on 2 this. 3 BY MR. BONELLA: 4 Q No opinion? Okay. 5 If Dr. Burks testified that the 6 difference -- differences between suture A and suture 7 B were subtle, would that affect your opinion? 8 MR. TAMBURIO: Objection, vague. 9 A No. I go by his final conclusion. 10 BY MR. BONELLA: 11 Q Well, at his deposition when he was 12 deposed and he was asked questions about the 13 difference between suture A and suture B, if he said 14 the differences between suture A and suture B were 15 subtle, would that affect your opinion? 16 A Sir, I -- 17 MR. TAMBURIO: Objection, vague. 18 Objection, vague, and mischaracterizes testimony. 19 A Sir -- sir, I was not in the deposition. 20 And again, hypothetical question. I do not have any 21 opinion, any hypothetical questions. 22 BY MR. BONELLA: 23 Q You have no opinion? 24 A No. 25 Q If Dr. Burks said the differences between</p>

<p style="text-align: right;">506</p> <p>1 suture B with suture B were subtle -- well, let me 2 back up. Did you -- have you been shown Dr. Burks' 3 deposition transcript? 4 A No. 5 Q No? Would you like to see it? 6 A No. 7 Q Why not? 8 A Because that's not relevant in my report 9 here. 10 Q It's not relevant to your opinions? 11 A I mean right now, what I'm going right 12 through. 13 Q Is Dr. Burks' deposition transcript 14 relevant to your opinions? 15 A Based on the -- I was -- I was informed 16 and, as I reported here, that's all I -- I can do 17 right now. 18 Q Okay. The question is a yes-or-no 19 question. Is Dr. Burks' deposition transcript 20 relevant to your opinions? 21 MR. TAMBURIO: Objection, calls for a legal 22 conclusion. 23 A No. I rely on the expert report. 24 BY MR. BONELLA: 25 Q Okay. Would you -- if he said in his</p>	<p style="text-align: right;">508</p> <p>1 mischaracterizes the testimony, incomplete 2 hypothetical. 3 BY MR. BONELLA: 4 Q So you don't want to know what his 5 testimony was about the tests? 6 MR. TAMBURIO: Objection, mischaracterized 7 the witnesses testimony. 8 A Correct. I don't want to know. 9 BY MR. BONELLA: 10 Q And you don't want to know what Dr. Burks 11 testified about how he actually did the test in his 12 deposition? 13 A No. 14 Q And do you know want to know how Dr. Burks 15 described the results that he obtained from the test 16 in the deposition? 17 A No. 18 Q "No," meaning you don't want to know? 19 A That's correct. 20 MR. BONELLA: Let's take a quick break. 21 THE VIDEOGRAPHER: Now going off the video 22 record at 11:04 a.m. 23 (A recess was taken from 11:04 a.m. 24 through 11:18 a.m.) 25 THE VIDEOGRAPHER: We're now back on the</p>
<p style="text-align: right;">507</p> <p>1 deposition that the differences between suture A and 2 suture B were subtle, is that information you'd like 3 to consider in forming your opinions? 4 A No. 5 MR. TAMBURIO: Objection. 6 BY MR. BONELLA: 7 Q Why not? 8 MR. TAMBURIO: Mischaracterizes the 9 testimony, vague question, and calls for legal 10 conclusion. 11 BY MR. BONELLA: 12 Q Why not? 13 A Again, I go by his expert report that he 14 saw the difference. That's the only thing that I can 15 go by so I cannot answer your question, no. 16 Q If he -- if he described the differences 17 between suture A and suture B as subtle and it was 18 even with gloves off, is that something you'd like to 19 know? 20 MR. TAMBURIO: Objection, vague. 21 A No. 22 MR. TAMBURIO: Mis -- give me a chance to 23 object. 24 THE WITNESS: Okay. Sorry. 25 MR. TAMBURIO: Okay? Objection, vague, and</p>	<p style="text-align: right;">509</p> <p>1 video record. The time is 11:18 a.m. and this is the 2 start of tape two, volume two in the continuing 3 deposition of Debi Prasad Mukherjee. 4 (Exhibit No. 364 was marked.) 5 (Exhibit No. 365 was marked.) 6 BY MR. BONELLA: 7 Q Dr. Mukherjee, we've marked what counsel 8 has produced for inspection here at the deposition as 9 DePuy Mitek Exhibit 364 is a suture that -- in a bag 10 that's labeled as uncoated, and Exhibit 365 is a 11 suture in a bag labeled as coated. Do you see those? 12 A Yes. 13 Q Are those the sutures that you performed a 14 drape test on? 15 A Yes. 16 Q Now, the drape test that you performed, is 17 there any literature that describes drape tests? 18 A No, this is just a very subjective test. 19 And I just wanted to get a feel for that. That's why 20 I did. It's not scientific. 21 Q Is the drape test that you performed, is 22 that subject to peer review? 23 A No, it isn't. 24 Q No? Okay. Can you show me -- well, let 25 me back up. When you were given the samples to</p>

24 (Pages 506 to 509)

<p>538</p> <p>1 Q Okay. Just a person that has an under 2 graduate degree -- 3 A Yeah. 4 Q -- in computer science, right? And if 5 that person then has written programming for 6 manufacturing of fibers, he's written programming code 7 to operate machines, would he be a person of ordinary 8 skill in the art? 9 MR. TAMBURIO: Objection, vague. 10 A With the three to five-year experience in 11 manufacturing, processing of fibers and sutures, yes, 12 the answer will be if they have this. 13 BY MR. BONELLA: 14 Q So -- 15 A I didn't say -- I didn't mean that 16 somebody's coming out of -- from the school, they're 17 going to turn into a -- a suture processing expert. 18 He has to spend three to five years. 19 Q Right. I'm talking about -- my question 20 is would someone with an undergraduate degree in 21 computer science -- 22 A Yes. 23 Q -- and three to five years of writing 24 computer code for manufacturing fibers and sutures for 25 machines, would he be one of ordinary skill in the art</p>	<p>540</p> <p>1 I never said the word "braiding" here. 2 Q Okay. 3 A You said the word "braiding." 4 Q I know. I'm asking a question. 5 A Manufacturing, processing of fibers and 6 sutures. If he has done that, yes, then he comes in 7 that definition. 8 Q But the person I just described you're 9 saying doesn't come under that definition? 10 A It -- it's -- if you -- if that's 11 considered any of these under manufacturing and 12 processing of fibers and sutures. 13 Q Well, those are your words so I'm trying 14 to find out whether you consider a person of three to 15 five years' experience in just operating braiding 16 equipment for sutures and that person has an 17 engineering or science degree, whether that person 18 falls within your definition of a person of ordinary 19 skill in the art. 20 MR. TAMBURIO: Objection, vague. 21 A No. 22 BY MR. BONELLA: 23 Q No? Okay. Is a -- a person who has an 24 engineer or science degree and just ran all the 25 manufacturing equipment that's needed to make a</p>
<p>539</p> <p>1 under your definition? 2 MR. TAMBURIO: Objection, vague. 3 A Not writing a computer code, because you 4 don't write computer code in order to make sutures. 5 BY MR. BONELLA: 6 Q Well, you can for some equipment. 7 A That -- what? 8 MR. TAMBURIO: Objection. That's not a 9 question. 10 A In my -- on my experience, no. 11 BY MR. BONELLA: 12 Q No? 13 A It's a very basic, you know, industry 14 where you don't have that highly sophisticated 15 computer program is required a lot of times. He has 16 to learn how to make the fibers, how to make the 17 sutures. That's my experience. If he has those 18 things, yes, they fit in here. 19 Q Well, a person of ordinary skill in the 20 art who had an undergraduate degree, any undergraduate 21 degree in engineering science, and spent three to five 22 years just operating braiding equipment for braiding 23 sutures, would he be a person of ordinary skill in the 24 art under your definition? 25 A No, because he's not just braiding. I</p>	<p>541</p> <p>1 suture, is that a person of ordinary skill in the 2 art -- 3 MR. TAMBURIO: Objection, objection, vague. 4 BY MR. BONELLA: 5 Q -- under your definition? 6 A Yes. 7 Q Okay. Is a person who has engineering 8 science degree and his only experience is in extruding 9 fibers for use in sutures a person of ordinary skill 10 in the art? 11 A The answer is yes. 12 Q Did you consider -- what -- do you have an 13 opinion on what direct intertwining contact as used in 14 the Hunter patent claims means? 15 A Yes. 16 Q Okay. And did you read the prosecution 17 history of the Hunter patent to figure that out? 18 A I know braiding so I know intertwining 19 contact means. 20 Q So if something -- if there's a -- a yarn 21 in a core and yarn in the sheath, as the yarn in the 22 sheath goes about the core is the yarn in the sheath 23 in direct intertwining contact with the yarn in the 24 core? 25 MR. TAMBURIO: Objection, vague.</p>

EXHIBIT 8



US005314446A

United States Patent [19]

Hunter et al.

[11] **Patent Number:** 5,314,446[45] **Date of Patent:** May 24, 1994[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] **Inventors:** Alastair W. Hunter, Bridgewater;
Arthur Taylor, Jr., Plainfield, both of
N.J.; Mark Steckel, Maineville, Ohio

[73] **Assignee:** Ethicon, Inc., Somerville, N.J.

[21] **Appl. No.:** 838,511

[22] **Filed:** Feb. 19, 1992

[51] **Int. Cl.⁵** D04C 1/00

[52] **U.S. Cl.** 606/231; 606/228;
87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231;
87/7, 8, 9; 428/225

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3,527,650	9/1970	Block	117/7
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3,942,532	3/1976	Hunter et al.	128/335.5
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4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
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Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

U.S. Patent

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Sheet 1 of 3

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FIG-1

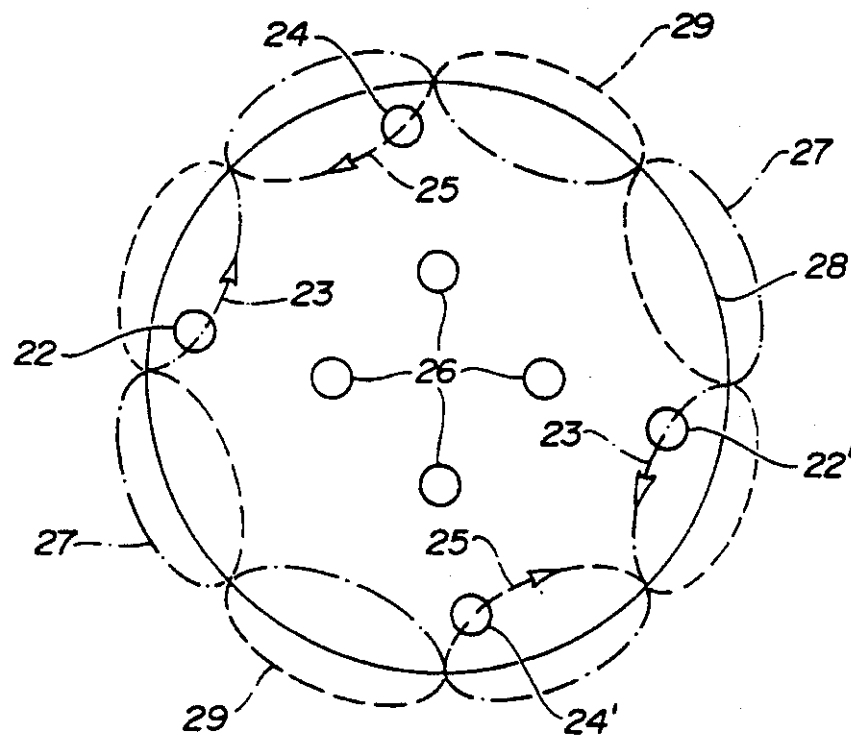


FIG-2

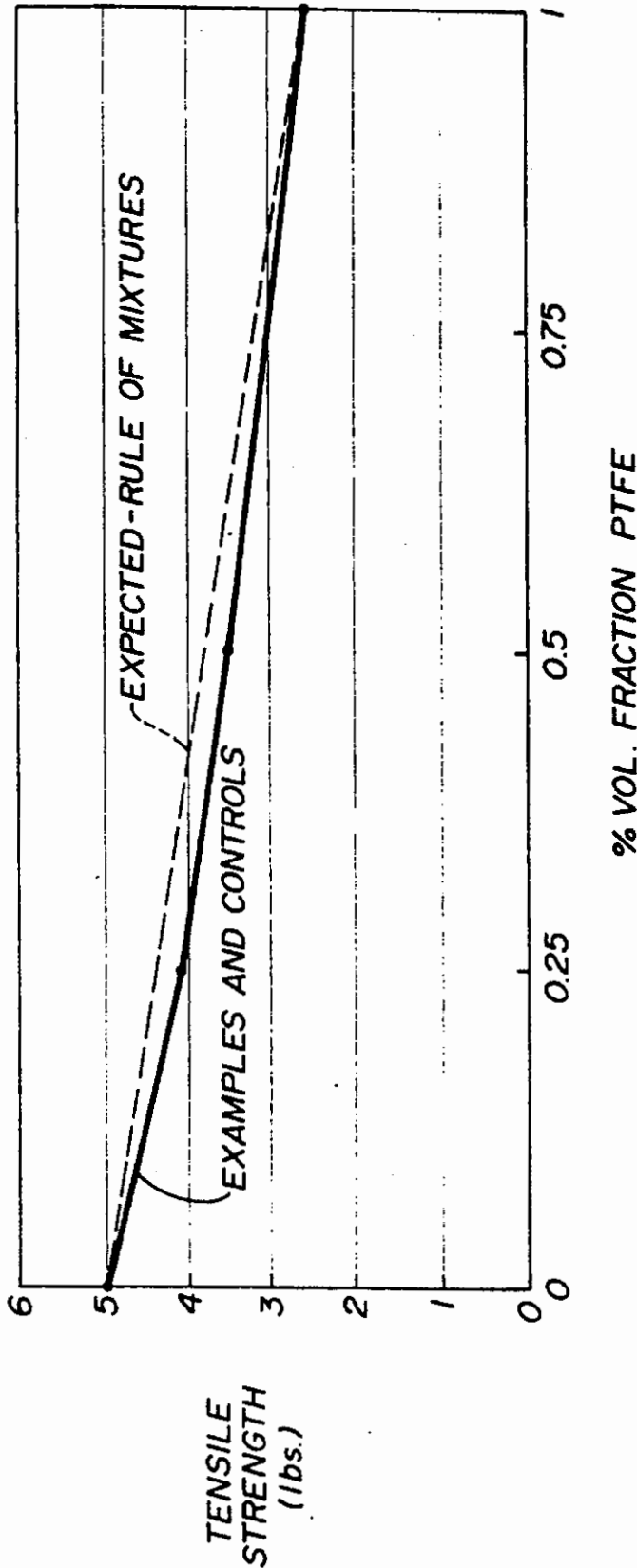
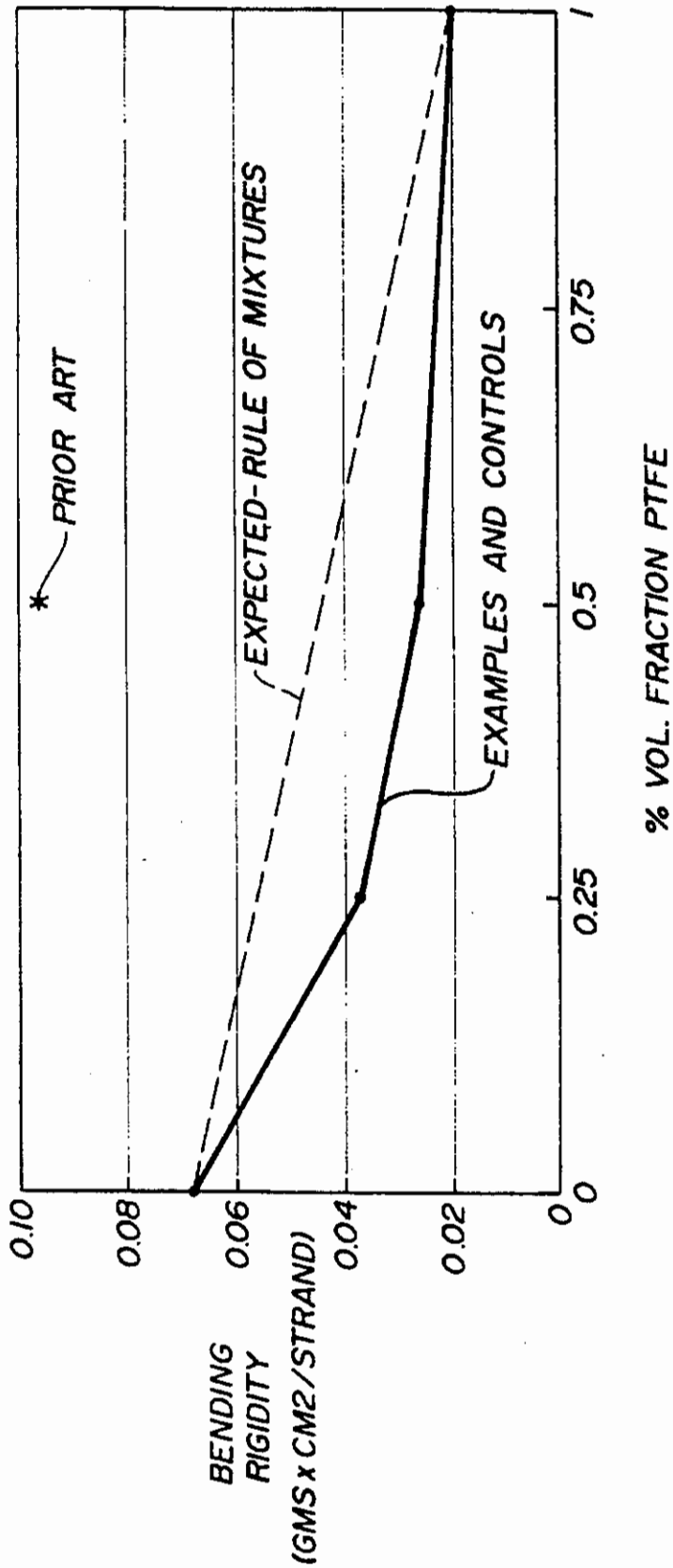


FIG-3



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STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

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the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

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ϵ -caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Dekker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

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24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

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CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm ²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (V_f)_a (P_a) + (V_f)_b (P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and $V_f)_a$ and $V_f)_b$ are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the bending moment-radius of curvature plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

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- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
 - b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
 - c) optionally a core.
2. The surgical suture of claim 1 wherein the suture is attached to a needle.
3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.
4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.
5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

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6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

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EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

REBUTTAL EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his rebuttal expert report as follows.

Dated: April 13, 2006

Debi P. Mukherjee
Debi Prasad Mukherjee, Sc. D.

EXHIBIT 6

(12) UK Patent Application (19) GB (11) 2 218 312 A

(43) Date of A publication 15.11.1988

(21) Application No 8911088.8

(22) Date of filing 15.05.1989

(30) Priority data

(31) 8811498

(32) 14.05.1988

(33) GB

(51) INT CL'

A01K 01/00, D04C 1/12

(52) UK CL (Edition J)

A1A A19

D1K K14

U18 81022

(56) Documents cited

None

(58) Field of search

UK CL (Edition J) A1A, D1K

INT CL' A01K, D04C

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(72) Inventor

Paul David Burgess

(74) Agent and/or Address for Service

Wynne-Jones Lliné & James

Morgan Arcade Chambers, 33 St. Mary Street, Cardiff,
Glamorgan, CF1 2AS, United Kingdom

(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyester or and/or nylon, and the braid may be coated with a sheath of polyurethane.

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"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

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It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple
5 and smooth sheath of polyurethane and this may
be carried out by a simple immersion-process in
liquid polyurethane. It will alter the
characteristics (such as buoyancy and strength)
in a predictable manner, but its main purpose is
10 to prevent saturation of the interstices of the
braid. In very cold conditions, such as fishing
through holes in ice, water having worked its
way into the braid will freeze and impart a
brittleness that can lead to breakage.

SL/SCS

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000124

-3-

CLAIMS

1. A fishing line of braided construction, some braid filaments being of high tenaxile polythene thread and other filaments being of polyester and/or nylon.

5 2. A line as claimed in Claim 1,, wherein the other filaments include polyester multi-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monofilaments.

4. A line as claimed in Claim 1., 2 or 3, wherein
10 the braid is coated by a sheath of polyurethane.

5. A line as claimed in any preceding Claim, wherein the polythene is that sold under the Trade Mark DYNEEMA.

-3-

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Sales Branch, St Mary Cray, Orpington, Kent BR6 3RD. Printed by Multiplex Technopress Ltd, St Mary Cray, Kent, Con. 1/67

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000125

EXHIBIT 7



ETH-78

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: 838,511 ✓

Art Unit: 1504

Filed : February 19, 1992 ✓

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 6, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

(Signature)

August 6, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

RECEIVED
AUG 17 1992
GROUP 150

AMENDMENT

Dear Sir:

Responsive to the Office Action of July 8, 1992, please reconsider the above-identified application in view of the following remarks.

REMARKS

1. Restriction to the invention of either Group I, claims 1-20, or Group II, claims 21-24, was required. Applicants reaffirm without traverse to prosecute the invention of Group II, claims 21-24. This election is made without prejudice to Applicants' right to file a divisional application directed to the non-elected invention of Group I, claims 1-20.

2. Claims 21-24 were rejected under 35 USC §103 as being unpatentable over Burgess. The Examiner has asserted that it would have been obvious in view of Burgess to use a heterogeneous braid for a suture. Applicants respectfully traverse this rejection.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000194

The Examiner mistakenly believes that the requirements for a braided suture are comparable to those of a fishing line. However, nothing could be further from the truth.

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement may be the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact. If the knot fails, then the wound can reopen and consequently the braided suture has failed as well.

Applicants recognized the importance of knot strength when attempting to overcome the shortcomings of the braided sutures disclosed in the art. In preferred embodiments of the invention, Applicants' claimed suture exhibits improved handling properties without sacrificing physical strength or knot security (see the specification at page 5, lines 4-7). In addition, numerous braided sutures were tested to determine their knot strength and knot security (see the examples at the end of the specification). The determination of knot security is described in the specification at page 12, lines 26-33.

In contrast, knot strength is not even mentioned in Burgess. Although it may be argued that it may be necessary to secure a knot on a fishing line to hold the hook to the line, the security and strength of the knot are not nearly as critical for this application. In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below.

Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability (see Burgess at page 1, lines 12-13). Although this thread has great strength properties, it suffers from

low elongation and in turn, poor knot strength. This is a good idea for a fishing line because high strength and low elongation, or low stretchability, are important criteria. Low elongation is an important requirement for a fishing line because it makes it possible for the fisherman to apply force on the hook when, for example, the fish is caught. If the line were stretchable, then the force exerted by the fisherman would be taken up by the stretching action of the line. This would clearly be an undesirable property for a fishing line to exhibit. Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security.

In addition to the contrasting requirements for braided sutures and fishing line resulting from the critical need to tie strong and secure knots on braided sutures, other requirements concerning the knot make the braid for a fishing line unsuitable for use as sutures. For example, a surgeon must be able to make a conventional square knot at a very fast pace for patient safety. Clearly, a knot on a fishing line for a hook can be made at a much slower pace, and with a much more complex knot. Also, it is necessary during suturing to form a pre-knot on the braided suture, and the pre-knot must be subsequently slid down the suture until it is adjacent the body tissue desired to be stitched. Once the knot is placed at the desired location, additional throws on the knot can be added for knot security. This requires a braided suture which is stretchable and resilient so that this operation can be performed. Obviously, there is no such similar requirement for a fishing line.

In view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a

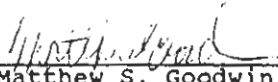
suture, then he would inevitably design an unpatentable suture. Accordingly, Applicants respectfully submit that the rejection is in error and therefore it should be withdrawn.

It is noted that the Examiner has discussed German Patent Application DE 2949920 A 1 and Ohi et al. as evidence of the state of the art concerning the types of filaments used in braided sutures, and core/sheath braid construction. Applicants do not wish to rely on these specific limitations set forth in claims 22 and 24 for patentability, but instead rely on the inventive features set forth in the broader independent claim, claim 21.

Accordingly, for the reasons set forth above, Applicants respectfully request the Examiner to withdraw the rejection of claims 21-24 under 35 USC 103 as being unpatentable over Burgess.

3. Since all formal requirements appear to have been met, except for the submission of formal drawings, and claims 21-24 are patentable over the art of record, Applicants respectfully solicit a Notice of Allowability.

Respectfully submitted,


Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

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One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

EXHIBIT 8

An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture

Bruce E. Cohan, MD; Jan W. Leenslag, MSc; Jon Miles; Albert J. Pennings, PhD

* An ultrastrong polyethylene fiber was evaluated as an ophthalmic suture. Properties of this fiber and of nylon, polypropylene, and polyester sutures were measured by standard techniques for fiber testing and for testing knot characteristics of sutures. Their behavior in cataract and keratoplasty surgery was assessed qualitatively. The ultrastrong polyethylene fiber has great tensile strength, high flexibility, and is very inelastic. Its strength and knot security provide safe incision closure and it has good biocompatibility. Ultrastrong polyethylene fiber is potentially superior to nylon, polypropylene, and polyester in the most important characteristics of a non-absorbable monofilament polymer ophthalmic microsuture.

(*Arch Ophthalmol* 1985;103:1816-1821)

In the 1960s, when the surgical microscope dramatically transformed surgery of the anterior segment of the eye, the most advanced suture material was the 40- μ m (8-0) twisted multifilament virgin silk of Barraquer. Silk has excellent handling and knotting characteristics because it is very flexible and inelastic, and it has a highly textured surface. Surgeons using it as a microsuture were dissatisfied with it, however, because they believed

that its strength was not adequate and they considered it too large for microsurgery. Also, since silk is of biologic origin, it causes significant tissue reaction; this and its biodegradability further limit its effectiveness in maintaining security of incision closure.

Microscopic eye surgery required a better suture material. In the early 1960s, the synthetic polymer, nylon, led to a further transformation in eye surgery. Undyed 40- μ m nylon monofilaments were first used in eye surgery at the University of Tübingen in Germany.¹ Subsequently, 25- μ m black-dyed nylon was provided by manufacturers, and for most eye surgeons it soon replaced silk because it was so much finer, stronger, and more inert. Although handling and knotting nylon sutures is more difficult because they are less flexible, more elastic, and smoother than silk, surgeons soon adapted to these characteristics. Two polymer monofilament sutures for eye microsurgery subsequently appeared that are comparable to nylon in their strength, flexibility, elasticity, and biocompatibility—polypropylene in the 1970s and polyester in 1983—but nylon continues today to be by far the most commonly used suture for anterior segment surgery.

Sutures of a fourth polymer, polyethylene, have also been available, but they have not been used for eye surgery. Histologic studies of polyethylene sutures have shown that they produce minimal tissue reaction, comparable to that of nylon, polypropylene, and polyester.^{2,3} Polyethylene is

widely used in orthopedic surgery as a replacement material for artificial hip-joint and knee components because of its excellent mechanical properties, biocompatibility, and biostability.^{4,5}

Recently, ultrastrong polyethylene fibers have been produced with new methods of polymer processing.¹ These fibers have a tensile strength of up to 4.7 times greater than that of comparable steel wire, and they are also very inelastic and very flexible.

In this study, we evaluated ultrastrong polyethylene fibers in comparison with nylon, polypropylene, and polyester ophthalmic sutures by (1) measurement of mechanical properties with standard fiber-testing techniques, and (2) qualitative assessment of their behavior as sutures during their use in cataract and keratoplasty surgery, and of the appearance on postoperative examinations of the tissue response and of the fiber itself.

MATERIALS AND METHODS

The ultrastrong polyethylene fibers used in this study were made from an ultra-high-molecular weight source material, Hi-Fax 1900 linear polyethylene, having a weight-average molecular weight of about 4×10^6 kg/kmole. The fibers were produced by hot-drawing of filaments obtained by a process of crystallization from flowing solutions of the polymer ("surface growth" technique). Details of these processes are described elsewhere.^{1,2}

The polyethylene fibers are monofilaments with a ribbon shape. The nylon, polypropylene, and polyester ophthalmic sutures evaluated are round monofilaments; they were taken from commercially purchased packages of 10-0 sutures for

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Accepted for publication Aug 2, 1985.

From the Eye Research Fund Laboratory, University of Michigan, Ann Arbor (Dr Cohan and Mr Miles), and the Laboratory of Polymer Chemistry, University of Groningen, the Netherlands (Dr Pennings and Mr Leenslag).

Reprint requests to the Eye Research Fund Laboratory, University of Michigan, 2350 Washtenaw Ave, Ann Arbor, MI 48104 (Dr Cohan).

operating room use of black Ethllon, blue Prolene, and green Mersilene, respectively (Ethicon Inc).

Mechanical Testing

Suture sizes are given designations based on their diameters, on the assumption they are round; those with a diameter of from 20 to 29 μm are designated as 10-0 according to the *US Pharmacopoeia*.¹⁴ The cross-sectional area of each of the four fibers has to be taken into account in comparing the results of mechanical properties testing. The cross-sectional area was determined under exclusion of pores by dividing the mass per unit length by the density of the material, assuming for polyethylene, 1,000 kg/cu m; for nylon 6/6, 1,180 kg/cu m; for isotactic polypropylene, 900 kg/cu m; and for polyester (polyethylene terephthalate), 1,457 kg/cu m. To show the shape and structure of the polyethylene fibers, specimens were gold coated and then examined in a scanning electron microscope, operated at 20 to 40 kV.

The standard method for determining the mechanical properties of a suture is by measuring its response to an applied load according to the procedure specified by the *US Pharmacopoeia*.¹⁴ Each end of the fiber is held by a clamp in a tensile strength testing machine. One clamp is connected to a motor-driven screw that loads the fiber by separating the clamps at a constant speed, and the other clamp is attached to a force gauge. The response of a fiber (at each point during the loading) is expressed as stress, which is the measured force divided by the cross-sectional area, and strain, which is the measured elongation. The appropriate unit of stress for monofilaments¹⁴ is the gigapascal (GPa), which is equivalent to 1,000 newton/sq mm; strain is reported as percentage increase in length of the specimen. The result of this testing is a "stress-strain curve" and the tensile strength of a fiber is the stress at the end of the curve, the point at which the fiber breaks. From the stress-strain curve of a material is derived the modulus of elasticity (Young's modulus, E), a constant in the equation relating stress to strain.

The mechanical properties of the fibers in this study were measured dry and at room temperature using a tensile strength tester with pneumatic clamps (Instron, models 1195 and 2712-002). The distance between the clamps and the clamp separation speed was 10 to 12 mm/min. The values presented are the average of five tests; measurement error is about 0.02 GPa. The configuration of knots tested in this study is described by a code¹⁵ in which the number of turns for each throw is indicated in numerals and the manner of joining the throws is shown by = for in parallel (square) and X for crosswise (granny).

The basic stress-strain curves for fibers of each of the four materials tested were obtained with a continuous, unknotted specimen loaded in the axial direction of the fiber; tensile strength is the end point, the point at which the fiber breaks.

A second series of stress-strain curves

was obtained by loading the ends of a single, continuous fiber that is tied with a surgical knot (2 = 1) around flexible rubber tubing of 6.5-mm inside diameter and 1.6-mm wall thickness.¹⁴ These curves show the weakening effect of a knot on each fiber; the knot pull strength is the end point, the point at which fibers knotted in this way break.^{14,15}

A third series of stress-strain curves was obtained by loading a specimen of two segments of a fiber joined by a knot. It is prepared from a single continuous fiber by first tying a knot of the configuration to be tested around a tube and then cutting the loop thus formed, yielding a specimen of two strands joined by the knot. These stress-strain curves give an indication of the security of that particular knot configuration with that fiber; knot holding strength is the end point, the point at which the knot breaks or slippage through the knot is observed.

Although there are no standard methods to describe quantitatively the important property of suture flexibility, it is related to torsional stiffness which can therefore be used as an approximate measure of flexibility.¹⁶ Fibers of the four materials equal in length (0.245 m) were held vortically and loaded with a weight (0.5×10^{-2} kg) attached at one end. The upper end of the fiber was rotated until the weight also started to rotate. The number of turns a fiber takes before the weight starts to rotate constitutes a relative measure of its flexibility. Because silk has always been highly valued for its excellent flexibility, it was also tested in this way. Because the finest-diameter silk suture commercially available is 9-0 black twisted virgin silk (Ethicon), specimens of it were compared with polyethylene fiber of about the same cross-sectional area.

Clinical Evaluation

The performance of the ultrastrong polyethylene fiber as an ophthalmic suture was evaluated qualitatively by observing its behavior during surgery. Its biocompatibility and functional adequacy after surgery were assessed, also in a qualitative way, on postoperative examinations. These observations were compared with prior experience in cataract surgery with the nylon in several thousand operations and the polypropylene in several hundred operations, and with subsequent experience with the polyester in several hundred operations. The comparisons in the keratoplasties were with several dozen in which the nylon was used.

Between February 1982 and April 1984, the polyethylene fiber was used to close 237 corneoscleral cataract incisions and, in nine patients, for penetrating keratoplasty. In the cataract operations it has also been used for suturing iris and conjunctiva. Lengths of the undyed ribbon-shaped polyethylene fiber having a width of 37 μm and a thickness of 15 to 25 μm were threaded and tied to an eyed "flat-lancet point" needle; this needle has a wire size of 150 μm , a 4-mm chord length, and a $\frac{1}{2}$ curve; its eye is 60 x 250 μm . For corneos-

cleral incision closure, after placing a central apposition suture, a continuous chain¹⁷ (running interlocking¹⁸) suture was used. A single continuous running suture was used in the keratoplasties. All knots were of the 3 = 2 = 1 "reinforced" configuration.¹⁹

During Surgery.—The response of the polyethylene fiber to the three basic suture-related surgical maneuvers (placement, tightening, and knot tying) was assessed during surgery on the basis of the usual visual and kinesthetic observations. Among the mechanical properties evaluated that affect a suture's handling characteristics are tensile strength, shear strength, compressive strength, elasticity, flexibility, and surface friction. Tensile, shear, and compressive strength affect a suture's behavior during pulling, bending, and grasping, respectively; elasticity, flexibility, and friction are factors in suture response to stretching, bending, and tissue drag, respectively.

During suture placement, as it is pulled through the needle track, the suture is subject primarily to tensile stress, acting along the direction of pull. Shear stress occurs near the point of attachment of suture to needle, whether it is swaged or threaded through an eyed needle. Resistance to pull-through affects the amount of tensile and shear stress in the suture. Surface friction and flexibility of a suture material are factors in the pull-through resistance of the suture as it enters, follows, and exits the suture canal.²⁰

During suture tightening, in addition to visual cues of tissue stress, proper apposition pressure is achieved by sensing the reaction force in the suture. Elasticity contributes to the suture tension, and this affects the kinesthetic estimation of incision closure pressure. In addition to tensile and shear stress in the suture, during tightening there is also the compressive stress from the forceps grasp.

The behavior of the fiber during knot tying was also observed and is also determined by several mechanical properties. Tensile, shear, and compressive strengths are necessary to maintain the integrity of the knot as it is tied. Flexibility and surface friction determine the amount of force required for knot tying and also the tendency of the knot to slip and become too tight.

Postoperatively.—The tissue response to the polyethylene suture and the appearance of the suture itself were assessed on routine postoperative evaluations beginning on the first day after surgery. Irritative symptoms were evaluated and then slit-lamp examination was performed.

In the cataract cases, the early postoperative reaction is obviously due primarily to the conjunctival dissection and the presence of the conjunctival suture, and the conjunctival flap often limits the visibility of the corneoscleral suture. With removal of the conjunctival suture, the conjunctival reaction subsides in a relatively predictable way unless the response to the corneoscleral suture prolongs it. As visualization of the corneo-scleral suture improves, any possible isolated response of the

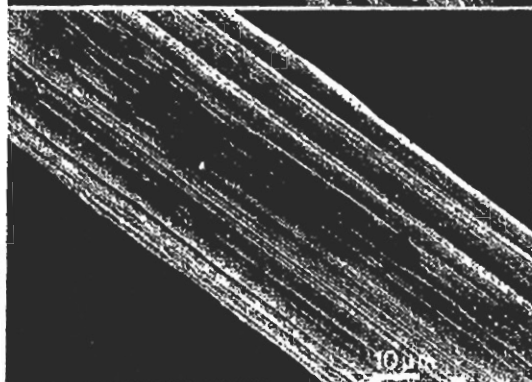
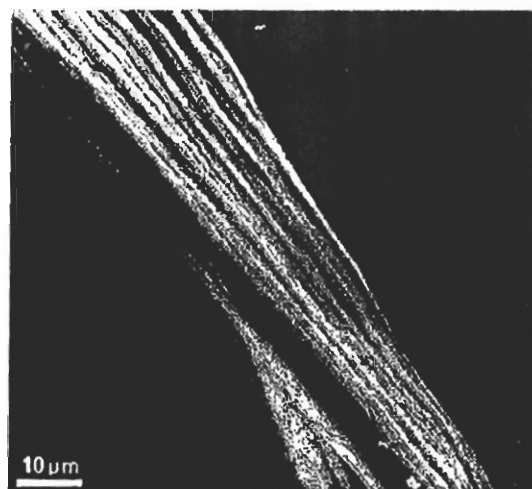


Fig 1.—Scanning electron micrograph appearance of ultra-strong polyethylene fiber: top left, ribbon shape of fiber; bottom left, smooth fibrillar structure of fiber; bottom right, lateral connections between fibrils.

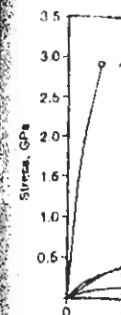


Fig 2.—Tensile stress-strain curves obtained from specimens of polyethylene (A); polyester (B); polypropylene (C) illustrate much variation at break with sutures. A indicates piggyback.

Material
Polyethylene
Nylon
Polypropylene
Polyester

* GPa indicate

Material
Polyethylene
Nylon
Polypropylene
Polyester

* GPa indicate

corneoscleral tissue to it may then be evaluated. The appearance of the corneoscleral suture itself is limited by the basic transparency of the conjunctival flap, and the dyed sutures are more easily visualized through the conjunctiva than is the undyed polyethylene. In the keratoplasties, both the effect of the suture on the cornea and the appearance of the suture itself were assessed from the first postoperative evaluation the day after surgery.

RESULTS

The scanning electron microscopic appearance of the polyethylene fiber that was used in this study shows its ribbonlike shape (Fig 1, top left), its highly fibrillated structure (Fig 1, bottom left), and lateral connections between fibrils (Fig 1, bottom right).

Mechanical Testing

The cross-sectional area for each of the four polymer monofilaments were calculated to be 0.41×10^{-7} sq m for the polyethylene, 0.54×10^{-7} sq m for the nylon, 0.50×10^{-7} sq m for the polypropylene, and 0.62×10^{-7} sq m

for the polyester.

The basic stress-strain curves for fibers of the four materials illustrate the essential mechanical differences between the polyethylene fiber and the three sutures (Fig 2). The slope of the polyethylene fiber curve is markedly different from those of the nylon, polypropylene, and polyester sutures, which tend to group together. The end points of the curves show that the tensile strength of the polyethylene fiber is 2.90 GPa, compared with values of 0.51 to 0.72 GPa for the sutures; and the polyethylene showed 5% elongation at the break point, compared with 26% to 36% for the sutures. The Young's modulus of the polyethylene fiber is also many times greater than that of the other materials (Table 1).

The stress-strain curves obtained when fibers of the four materials are knotted also show a large difference between the polyethylene fiber and the sutures (Fig 3). The end points of the curves at which the knotted fibers break show that the knot pull

strength for the polyethylene fiber is 1.35 GPa, compared with values of 0.42 to 0.55 GPa for the sutures.

The stress-strain curves that result when segments of fibers of each of the four materials are joined by a knot with a 3-2-1 configuration also show differences similar to the previous two stress-strain tests (Fig 4). The end point of the knot holding strength test with this particular knot for the polyethylene fiber is 0.32 GPa, with slippage through the knot occurring at this level of stress, compared with the sutures that break at values of 0.48 to 0.53 GPa.

Several other knot configurations were tested to demonstrate the degree of knot complexity required for fibers of each of the materials to reach the approximate limit of knot security (knot pull strength), that is, the level at which a specimen of joined segments behaves as if it were a single, continuous fiber containing a knot (Table 2). The knot failure level of polyethylene fiber segments when

joined by a 4-4 knot pull strength. Polyethylene 4-4 knot pull strength. The three sutures can reach the knot pull strength when joined (2-2), and necessary to test materials with knots. Results of relative torsion

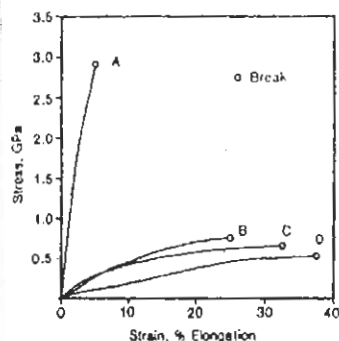


Fig 2.—Tensile strength. Stress-strain curves obtained from single continuous unknotted specimens of polyethylene (A); polypropylene (B); polyester (C); and nylon fibers (D). Curves illustrate much greater strength and less elongation at break of polyethylene fiber compared with sutures of other three polymers. GPa indicates gigapascal.

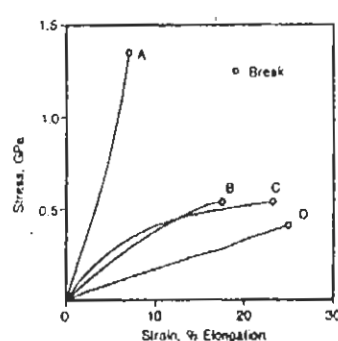


Fig 3.—Knot pull strength. Stress-strain curves obtained from single continuous knotted specimens of polyethylene (A); polypropylene (B); polyester (C); and nylon fibers (D). Curves show that even with knot, polyethylene fiber has much greater strength than sutures of other three polymers. GPa indicates gigapascal.

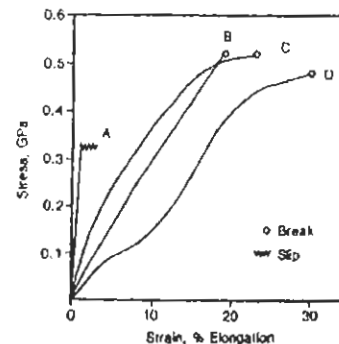


Fig 4.—Knot holding strength. Stress-strain curves obtained with a 3 = 2 = 1 knot (see text for explanation) joining two segments of polyethylene (A); polypropylene (B); polyester (C); and nylon fibers (D). Curve for polyethylene fiber shows slippage with this knot at strength level somewhat less than those at which sutures of other three polymers break. GPa indicates gigapascal.

Table 1.—Mechanical Properties and Cross-sectional Areas

Material	Tensile Strength, GPa*	Young's Modulus (E), GPa*	Elongation, %	Cross-sectional Area ($\times 10^{-8}$ sq m)
Polyethylene	2.90	72.0	6	0.41
Nylon	0.51	3.5	38	0.54
Polypropylene	0.72	5.3	26	0.50
Polyester	0.87	14.5	32	0.62

* GPa indicates gigapascal.

Table 3.—Torsional Flexibility and Cross-sectional Areas

Material	Turns, No.	Cross-sectional Area ($\times 10^{-8}$ sq m)
Polyethylene	120	0.41
Nylon	10	0.54
Polypropylene	5	0.50
Polyester	6	0.62
Polyethylene Ssk	18	0.99
	13	1.02

Table 2.—Knot Holding Strength for Different Knot Configurations and Knot Pull Strength

Material	Knot Configuration				Knot Pull Strength, GPa*
	2 = 2	3 = 2 = 1	4 = 1 = 1	4 = 4 = 4	
Polyethylene	...	0.32	0.35	0.65	1.35
Nylon	0.40	0.48	0.45	...	0.42
Polypropylene	0.52	0.52	0.60	...	0.65
Polyester	0.55	0.53	0.55	...	0.55

* GPa indicates gigapascal. See the text for an explanation of knot configurations.

joined by a 4 = 4 knot exceeds the knot pull strength of the three sutures. Polyethylene segments joined in the 4 = 4 = 4 knot configuration reach the knot pull strength for this material. The three sutures, on the other hand, can reach their knot pull strength when joined with simpler knots (2 = 2), and it was therefore unnecessary to test these conventional suture materials with the more complex knots.

Results of the test that measures relative torsional flexibility show that

the polyethylene fiber can take 12 to 24 times more turns than the sutures before the mass suspended by it begins to rotate (Table 3). Torsional flexibility is very sensitive to cross-sectional area and this is demonstrated by the marked decrease in flexibility of a larger polyethylene fiber. So the results for the three 10-0 polymer sutures should not be compared with the 9-0 silk suture; silk of comparable cross-sectional area would be much more flexible. When fibers of comparable cross-sectional

area are compared, however, the polyethylene is more flexible than the silk.

Clinical Evaluation

During Surgery.—Qualitative assessment of ultrastrong polyethylene fibers in both cataract and keratoplasty surgery revealed that it has remarkable strength in response to the tensile, shear, and compressive stresses that occur in pulling, bending, and grasping. The continuous suture closure of the cataract incision generally required eight to ten passes through the corneoscleral tissue; often more than 30 passes were used in a keratoplasty. This results in considerable stress during placement, tightening, and knot tying. And yet not a single break of the polyethylene fiber was encountered in any of these surgical procedures. In one instance the fiber was inadvertently cut by the sharp edge of the needle.

One effect of the remarkable strength (and also flexibility) of the polyethylene fiber is its resistance to shearing stress where it passes

through the eye of the needle. In only two instances did it break at this point of extreme bending despite the multiple passes through the tissue. Sutures of the other three polymers used with an eyed needle characteristically resist this bending for only a few passes before breaking. While using the polyethylene fiber, full confidence developed that the possibility of fiber break was not a factor during surgery. When this series was completed and subsequent surgery was performed using the other polymer sutures, the amount of stress that they could sustain without break had to be "re-learned."

An important property of the polyethylene fiber which is apparent during surgery is that it is very inelastic. This makes proper tension on the fiber easier to obtain during tightening a continuous suture and the first throw of a knot because of the negligible contribution of fiber stretch to the kinesthetic estimation of apposition pressure. The polyethylene fiber conducts mechanical tension so well that one obtains a direct sense of the tissue stress during tightening and tying.

Another attribute of the polyethylene fiber observed during its use as a suture is its flexibility. It tends to behave much like silk and without the kinks or corkscrew formations typical of the other polymers and thus handles more easily. It readily conforms to the tissue surface because it does not have a wiry springiness. The behavior of the polyethylene fiber at the eye of the needle illustrates its high flexibility: it can be tied to the needle with adequate security with a single throw. All three polymer sutures characteristically require a more complex knot because of the "unlooping" tension caused by their relative inflexibility.

The polyethylene fiber appears to have relatively low surface friction, and this agrees with measurements in a previous study that included polyethylene sutures.⁴ Although the polyethylene fiber has a flat cross section, high flexibility, and relatively low friction, no difference from the other suture materials in pull-through resistance (tissue drag) could be detected in its passage through corneoscleral or corneal tissue.

A definite limitation of the polyethylene fiber during its use in surgery was that it was undyed. For this reason it was used in 37- μ m-wide ribbons that appear larger than 10-0 round monofilaments. Undyed 25- μ m-wide polyethylene fibers were too fine for adequate visualization.

Finally, because of the polyethylene fiber's flat shape, its low friction, and its softness (with forceps compression it can become even flatter), handling the fiber requires tying forceps with jaws that properly appose in order to get enough traction for adequate tightening and tying tension. The characteristics that affect its tightening and tying, and its remarkable strength and flexibility, affect the cutting of it, and so sharp scissors with properly adjusted blades are necessary. Holding tension on the fiber makes it easier to cut because this prevents it from sliding between the scissors blades. Scissors used for cutting the polyethylene fiber tend to become dull sooner than when they are used for cutting the other polymer sutures.

Postoperatively.—Beginning the day after cataract surgery, from patients' descriptions of irritative symptoms and from slit-lamp evaluation of the response of conjunctiva, corneoscleral tissue, and iris, when it was sutured, no difference was distinguished in the biocompatibility of the polyethylene fiber when compared with the experience with the series of cataract operations in which the three commercially available polymer sutures were used. The polyethylene fiber provided good closure of the corneoscleral incision and resulted in the typical amount of early with-the-rule astigmatism that usually receded spontaneously to the desired level of less than 2 diopters. Occasionally, one or more of the limbs of the corneoscleral suture were cut with a blade fragment to relieve tension and reduce astigmatism, just as is done with sutures of the other polymers.

With the use of polyethylene fiber, rare instances were observed of spontaneous untying of the knot of the apposition suture or the beginning knot of the continuous corneoscleral suture, just as in the other series with the polymer sutures. But with the polyethylene fiber, the final knot of the continuous suture occasionally did spontaneously untie. The frequency of this phenomenon cannot be determined because of the variable visibility of corneoscleral sutures, especially of this undyed one. Untying of this knot was observed infrequently with the other, more visible, dyed polymer sutures: it is certainly more common with the polyethylene. When it was observed, this was generally a month or more after surgery. The explanation for this untying lies in the termination of a continuous chain suture: the knot is tied from the free end and

a bight (a loop) drawn from the last limb," resulting in a knot tied with three strands of the fiber instead of the usual two. Because of the high flexibility and low friction of the polyethylene fiber, two of the strands act like tracks, permitting the third to slip. In these instances, and throughout the entire series of cataract incisions closed with the polyethylene fiber, against-the-rule astigmatism that would occur with wound stretching was no more frequent than in the series in which sutures of the other three polymers were used.

A second occasional postoperative observation of both the continuous corneoscleral and keratoplasty sutures was the unravelling and exposure of exceedingly fine microfilaments from the edge of the fiber, usually within two months of surgery. This caused minor irritative symptoms that were eliminated by stripping the microfilament with a jeweler's forceps or cutting it with scissors; this had no effect on the security of the incision closure. Breakage of the fiber was never observed postoperatively.

After keratoplasty using the polyethylene fiber, from the first postoperative day, patients' complaints of irritation were much less than when this operation is performed using the other polymer sutures. Improved patient comfort continued even if an end of the single knot became exposed and also even when one or more limbs remained above the epithelial surface. This is due to its flat shape with a thickness of only several micrometers, its high flexibility, and its low friction. With the polyethylene fiber, knots are small and compact, and limbs readily conform to the shape of the corneal surface, lying flat up to each point of entry and exit. Suture-stimulated vessel ingrowth into the graft has not been observed, even where a knot or limb is exposed. Graft-host edge apposition is better controlled in the polyethylene fiber-sutured grafts, as indicated by fewer focal peripheral graft striae. This may be attributed to the fact that the fiber is very inelastic, which permits more precise estimation of suture tension during tightening.

COMMENT

There is good agreement between the results of the laboratory testing of the mechanical properties of the ultrastrong polyethylene fiber and the observations made during and after surgery. The polyethylene fiber has remarkably high tensile strength and

flexibility during surgery, eliminating most astigmatism in sutured corneal grafts on the testing polyethylene fiber. It was a very superior material. The ethylene glycol over the in Albo that some strong other knots realized

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flexibility. Suture break as a factor during both cataract and keratoplasty surgery with this fiber is actually eliminated in all the manipulations a continuous suture is subjected to—a most unusual attribute in an ophthalmic suture. Further, it is very inelastic in comparison with the other suture materials, and this permits especially sensitive control during suture tightening and tying. This characteristic is especially advantageous in keratoplasty because the graft position is critically dependent on the suture. In both the laboratory testing and in use during surgery, the polyethylene fiber showed great flexibility, a valuable attribute that gives it what surgeons of the premicrosurgery era would describe as "hand" superior even to the standard of that period—silk.

The knot pull strength of the polyethylene fiber is also high, which indicates the potential for superiority over conventional polymer sutures in the important aspect of knot security. Although laboratory testing showed that the polyethylene fiber has a somewhat lower knot holding strength with simpler knots than the other three polymers, more complex knots than are commonly used would realize polyethylene's great knot pull

strength. Considering the surprising security of this fiber when tied to an eyed needle with only a single throw, the conventional knot testing procedures may not provide a full characterization of the complex aspect of knot security.

Postoperatively, in cataract incision closure the polyethylene fiber showed the same biocompatibility characteristics as the sutures currently being used. The one situation in which knot security with the polyethylene is different from the other sutures was the occasional observation of knot slippage where three strands of the fiber are included in the knot of a continuous cataract incision closure suture, but this did not affect the security of incision closure.

Postoperatively, in keratoplasty the polyethylene fiber seems superior in every way to the commercially available sutures. Considering biocompatibility to include the effects on ocular tissue of its flat shape, high flexibility, and low surface friction, this fiber is superior as a suture for keratoplasty.

A minor inconvenience is the occasional unravelling of microfibrils from the fiber, sometimes causing irritation until they are removed. And obviously, this fiber is more difficult

to work with because it is undyed. Whether the polyethylene fiber will biodegrade over time cannot be determined at this time because of the limited period of follow-up; no evidence of it has been observed to the present.

Further refinements in the process of preparation of the ultrastrong polyethylene fiber may lead to its acceptance as an ophthalmic microsuture. First, it will be much easier to see during surgery because it has been successfully dyed so that 25- μ m-wide ribbons of it are as visible as 10-0 polypropylene (unpublished results). Second, the use of a "gel-spinning" process should yield a fiber with a more compact filament structure and thus eliminate the occasional unravelling of microfibrils.¹³ Finally, to increase the polyethylene fiber's surface friction, its surface texture might be improved by surface structuring.¹⁴

The authors do not have any commercial or proprietary interest in the ultrastrong polyethylene fiber discussed in this article and had no financial interest as evaluators of the ultrastrong polyethylene fiber.

The authors wish to thank Pek van Andel for his contribution to this study of fine ultrastrong polyethylene fibers and Tamara Dames for her assistance in preparing the manuscript.

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EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Rebuttal Expert Report of Dr. David Brookstein

I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.

4. If Dr. Mukherjee is correct regarding the meaning of “consisting essentially of” and the novel and basic characteristics of the invention, it is my opinion that FiberWire’s coating does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

5. If Dr. Mukherjee is correct regarding the meaning of “consisting essentially of” and the novel and basic characteristics of the invention, it is my opinion that the nylon in TigerWire does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

6. If Dr. Mukherjee is correct regarding the meaning of “consisting essentially of” and the novel and basic characteristics of the invention, it is my opinion that FiberStick’s adhesive does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

7. The reverse doctrine of equivalents does not prevent infringement.

8. I disagree with Dr. Mukherjee that FiberWire’s benefits, which Arthrex promotes, are almost exclusively due to the UHMWPE in FiberWire.

III. If PE Is Construed Not to Include UHMWPE, FiberWire Still Infringes Under the Doctrine of Equivalents

9. As I explained in my previous report, if “PE” as claimed in the 446 Patent is construed not to include “UHMWPE,” there is infringement under the doctrine of equivalents because the differences between UHMWPE and “PE” are insubstantial. Dr. Mukherjee has expressed opinions to the contrary. But I disagree with him for at least the following reasons.

10. As one basis for his opinion of substantial differences between “PE” and UHMWPE, Dr. Mukherjee opines that the 446 Patent describes the first fiber-forming materials as “lubricous but relatively weak” and alleges that the first fiber-forming materials are different than UHMWPE, which is known to have certain strength properties (Mukherjee Res. Report at 15). I disagree because the 446 Patent does not describe the first fiber forming materials as “lubricous but relatively weak.” In fact, it never describes the first fiber-forming materials, including “PE,” as

“weak.” Rather, in a preferred embodiment, the 446 Patent describes the first fiber-forming materials as acting “as lubricating yarns,” but not “weak” yarns (Ex. D at 4:11-12). UHMWPE is consistent with the description of the first fiber-forming materials in the 446 Patent. The 446 Patent describes that, in a preferred embodiment, the first yarns act as lubricating yarns (Ex. D at 4:11-12). PE, including UHMWPE, is a lubricious material (Ex. I at 52:24-53:1). Further, the 446 Patent explains that the first set of yarns may be “non-absorbable polymers” (Ex. D at 4:10-11). UHMWPE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber-forming materials (Ex. D at 2:45-46). UHMWPE is a fiber-forming material. Therefore, the 446 Patent’s description of the first-fiber forming materials is consistent with UHMWPE. Moreover, UHMWPE is consistent with the more general description of the invention, as set forth in column 2, lines 40-63, column 3, lines, 21-28, 40-65, and column 6, lines 50-56. Therefore, I disagree with Dr. Mukherjee’s opinion that the 446 Patent describes the first fiber-forming materials as “weak,” and I also disagree that the differences between UHMWPE and PE are substantial.

12. I disagree that the 446 patent describes the first fiber-forming materials as “weak,” as Dr. Mukherjee states (Mukherjee Res. Report at 15), for additional reasons. Dr. Mukherjee states that the 446 Patent describes the first fiber-forming materials as being “weak.” But this is incorrect. For example, the 446 Patent describes PE, which includes UHMWPE, as a first fiber-forming material, and UHMWPE was known to have certain strength attributes, such as tensile strength. Likewise, the 446 Patent describes polypropylene (PP) as a first fiber-forming material, and it is known to have certain strength attributes, namely tensile strength. This is described in the literature. For example, *Marks’ Standard Handbook for Mechanical Engineers*, a well known reference, describes polypropylene fibers as having a breaking tenacity of 4.0-7.0 gpd

(Ex. J). Further, U.S. Patent No. 4,413,110 describes certain polypropylene fibers as having a tenacity of at least about 8 gpd (Ex. K at 2:7-11). Also, the *Production and Applications of Polypropylene Textiles* states on page 54 that the breaking tenacity of polypropylene fibers is over 500 mNtex⁻¹ (Ex. L). Thus, certain polyethylene and polypropylene fibers are not “weak” in tensile strength. Thus, I disagree with Dr. Mukherjee’s statement that the first-fiber forming materials are all “weak.”

13. Dr. Mukherjee seems to indicate that the first fiber-forming materials are all necessarily “weak” in tension when compared to the second fiber-forming materials. But this is incorrect because polypropylene fibers, one of the first fiber-forming fibers, were known to have strength on the same order of magnitude of nylon and PET fibers, two of the second fiber-forming materials. For example, *Marks’ Handbook* describes polyester fibers, which I read as including PET, as having a breaking tenacity of 4.4-7.8 gpd, and nylon 6,6 fibers as having a breaking tenacity of 4.6-9.2 gpd (Ex. J). Further, the *Production and Applications of Polypropylene Textiles* states on page 54 states that the breaking tenacity of polyester fibers, which I read as including PET, is 350 mNtex⁻¹ (Ex. L). Using this information, PP has a breaking tenacity in the range of other well known relatively high-strength fibers such as polyester (PET) and nylon. Further, one fiber manufacturer describes the tensile strength of two first fiber-forming materials, PVDF and PP, as having about the same tensile strength as two of the second fiber-forming materials, nylon and PET. For example, it states that monofilament PVDF has a tenacity of 4.71 gpd, two monofilament polypropylenes have breaking strengths of 3.0 and 4.0 gpd, two monofilament polyesters (which I read as PET) as having a breaking strength of 4.5 or 6.0 gpd, and nylon monofilaments as having a breaking strength of 4.5-6 gpd (Ex. M; see also Ex. N). Consequently, the first fiber-forming materials are not all “weak” in tension in

comparison to the second fiber-forming yarns, and I disagree with Dr. Mukherjee's assertion that they are.

14. As another basis for his opinion of substantial differences, Dr. Mukherjee opines that the differences between the claimed "PE" (if PE does not include UHMWPE) and UHMWPE are substantial because the claimed second fiber-forming materials are "added for strength" and UHMWPE is added to increase FiberWire's strength. I understand that the relevant comparison is between PE and UHMWPE, not between the claimed second fiber-forming materials and UHMWPE. Thus, I am not sure why Dr. Mukherjee is comparing the second fiber-forming materials to UHMWPE. Nevertheless, I disagree with his statement that FiberWire's construction is the opposite of what is described in the 446 Patent. The 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. D at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire's UHMW PE is lubricous (Ex. I at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, "to provide improved strength to the heterogeneous braid" (Ex. D at 4:33-36). FiberWire is consistent with this description; FiberWire's PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. I at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,¹ of the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot.

¹ I use the term "knot pull strength" to refer to the force at which a suture having a knot tied in it fails when tested in a tension test (*see, e.g.*, Ex. O). I use the term "knot holding strength" to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Ex. P, Q. Knot holding strength is an indication of knot security. The 446 Patent describes another exemplary knot security test (Ex. D at 6:36-44).

Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

15. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. I at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (Ex. I at 45:16-46:15; 50:1-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (Ex. I at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (Ex. I at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (Ex. I at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. Accordingly, FiberWire's braid is not, as Dr. Mukherjee opines, the opposite of what is described in the 446 Patent.

16. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. R at 1:19-21; Ex. I at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. I at 26:24-27:2). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength.

According to Arthrex's 234 patent, this problem was overcome by braiding UHMWPE with polyester (Ex. R at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the "ability to approximate the tissue and hold it in place through biomechanical forces" (Ex. I at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester.

17. Dr. Mukherjee further opines that the differences are allegedly substantial between "PE" (if PE does not mean UHMWPE) and UHMWPE, as used in FiberWire, because UHMWPE is what makes FiberWire so strong (Mukherjee Res. Report at 16). I disagree. As explained above, although one might expect that UHMWPE provides certain strength attributes to FiberWire, namely, tensile strength, the PET adds certain strength characteristics as well, including knot holding strength. Notably, Arthrex discarded the idea of using a braid of just UHMWPE because it had poor knot holding strength characteristics, and braided PET with UHMWPE to increase the knot holding strength.

18. In support of his opinion regarding substantial differences, Dr. Mukherjee also performs a function/way/result analysis. I also disagree with this analysis. Dr. Mukherjee states that the "function" performed by the claimed first fiber-forming materials is "to add lubricity with the recognition that these materials will detract from the strength of the resulting suture" (Mukherjee Res. Report at 16). I disagree. The 446 Patent does not describe the function of the claimed first-fiber forming materials as "detract[ing] from strength." I disagree with Dr. Mukherjee's opinions regarding "detract[ing] from strength" for the same reasons that I stated above with reference to his opinions that the 446 Patent describes the first-fiber forming materials as "weak." Further, I disagree that his reference to column 4, lines 42-54, and a

variation of a single embodiment of a PTFE/PET braid is a statement that the first fiber-forming materials are “too weak for most suture applications” (Mukherjee Res. Report at 7). This section of the 446 Patent describes variations of single embodiment and does not discuss the use of the first fiber-forming materials in “most suture applications.”

19. Nevertheless, even if Dr. Mukherjee is correct about the “function” of the claimed first fiber-forming materials, UHMWPE, as used in FiberWire, performs the function of adding “lubricity with the recognition that these materials will detract from the strength of the resulting suture.” UHMWPE is a lubricous material that adds lubricity to the FiberWire braid (Ex. I at 52:24-53:1). Also, it is recognized that UHMWPE, due to its lubricity, detracts from certain strength characteristics, including knot holding strength (*see above*, Ex. R at 1:19-21; Ex. I at 104:9-15).

20. Although Dr. Mukherjee refers to the “way” and the “result” of the claimed first fiber-forming material, he never defines what they are. For example, Dr. Mukherjee states that the “result obtained by substituting UHMWPE for the first fiber-forming materials is substantially different.” But he does not provide his opinion regarding the “result” attributable to the claimed first fiber-forming materials and the “way” the first-fiber forming materials perform their function. Nevertheless, I disagree with his opinion that the “result” of using UHMWPE in FiberWire is limited to increasing strength. It also adds lubricity which enhances other FiberWire properties such as handleability. Also, he seems to attribute all of FiberWire’s strength properties to UHMWPE. I disagree with this opinion. PET also contributes to FiberWire’s strength properties, namely knot holding strength properties (Ex. R at 1:19-21,29; 2:50-52; Ex. I at 104:9-15). Further, even if FiberWire’s function is increasing tensile strength,

it is my opinion that the first fiber forming materials, such as PP, function to add tensile strength. Therefore, the differences are insubstantial.

21. Dr. Mukherjee disagrees with my opinion regarding equivalents because it is too broad. I believe that he misunderstands my opinion. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

IV. Under Dr. Mukherjee's Definition of "Consisting Essentially Of," FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

22. As I understand the law, because the 446 Patent claims recite the phrase "consisting essentially of," if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the "basic and novel characteristics" of the claimed suture. Dr. Mukherjee opines that the "basic and novel characteristics" of the suture claimed in the 446 Patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18, Section VI.D.). According to Dr. Mukherjee, FiberWire's coating, TigerWire's nylon visual marker strand, and FiberStick's adhesive, each provide a "material" affect on this novel and basic characteristic that precludes infringement (Mukherjee Res. Report at 22, 30, 31). I disagree with Dr. Mukherjee's opinion and address each of his three points below.²

² Mr. Grafton's testimony and Arthrex's 234 patent support my opinion regarding the equivalence of UHWMPE and PE if "PE" is defined not to include UHMWPE as well as my opinion that there is no material affect on the novel and basic characteristics as set forth in my previous report for the reasons set forth herein. For example, they show that the differences are insubstantial because UHMWPE provides lubricity and PET provides knot holding strength.

A. If the Novel And Basic Characteristics Have The Definitions Provided By Dr. Mukherjee, FiberWire's Coating Does Not Materially Affect Them

23. According to Dr. Mukherjee, the novel and basic characteristics are “a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties” (Mukherjee Res. Report at 18). Dr. Mukherjee opines that FiberWire's coating materially affects this novel and basic characteristic. I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a “material” affect on the basic and novel characteristics; and (iii) Dr. Mukherjee's tests are flawed or inconclusive. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

24. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface “lubricant” (Mukherjee Res. Report at Ex. 16).

25. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex's development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. I at 52:24-53:7). The homogeneous UHMWPE braid was too lubricous to "hold a knot" (Ex. I at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good "strength" properties (Ex. I at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (Ex. I at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. S). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. S; Ex. I at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

- Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
- A. Yes.
- Q. Yes?
- A. Yes.
- Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to

reduce the knot slippage?

A. Yes.

Q. And when you say knot slippage, we're referring to this knot security test?

A. Yes.

Q. So are we using the terms knot slippage and knot security interchangeably here?

A. You are, yes.

Q. In your testimony?

A. Yes.

Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?

A. Yes.

Q. And your idea was to add the PET and to improve the knot security?

A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. I at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. I at 68:25-70:13). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliability, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

26. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr.

Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the Ethicon sample)" (Ex. HH) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. HH). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

- Q. I would like to know what you mean by in your letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?
- A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
- Q. Wait a second. You said optimization of two materials.
- A. (Witness nods head affirmatively).
- Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
- A. During -- during the -- during that period of time, yes.
- Q. So you were balancing off the properties of each material to try to get the optimum properties --
- A. Tensile strength.
- Q. To get the optimum tensile strength?
- A. (Witness nods head affirmatively).
- Q. What about knot security?
- A. Yes.
- Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
- A. Yes.
- Q. Any other properties? Knot tiedown?
- A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
- Q. So you were varying type and proportion of the

materials to optimize all these properties in the product?

A. Yes.

(Ex. I at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?

A. All materials used.

(Ex. T at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

27. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasurable (Ex. U at 119:5-9; Ex. V at 94:2-9; Ex. W at 48:1-50:16; Ex. X at ARM2104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed³ and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters

³ Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

per minute (Ex. U at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. U at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. U at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. U at 95:14-17). The process is then repeated. I have measured the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DM Exhibits 284, 342, and 285). I determined that the linear density of Ex. 284 (uncoated) is 2393 denier, Ex. 342 (coated once) is 2474 denier, and Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from Ex. 342. Thus, the total pick-up of Ex. 285 over Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Mukherjee Res. Report at Ex. 16).

28. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

29. Dr. Mukherjee opines that the SEM's attached to my expert report are "too unclear to draw any conclusions from them" (Mukherjee Res. Report at 30). But Dr. Mukherjee concludes based on these SEM's that the "coating has permeated into the braid" (Mukherjee Res. Report at 30). I do not understand how Dr. Mukherjee can say the SEM's are "too unclear to draw any conclusions" then make conclusions from the very same "unclear" micrographs.

30. I note that Dr. Mukherjee does not opine on the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, he seems to opine that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as he defined the novel and basic characteristics. Rather, the relevant issue as he framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its

coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

31. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Dr. Mukherjee, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Dr. Mukherjee.

32. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. D at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (Ex. D at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

33. I disagree with Dr. Mukherjee's opinion that FiberWire's coating has a "material" effect because he basically *excludes* coated sutures from the 446 Patent claims (Mukherjee Res. Report at 22). But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to *further* improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. *Most preferably*, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating *may be* eliminated saving expense as well as avoiding the associated braid stiffening.

(Ex. D at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them, as Dr. Mukherjee opines. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

34. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Dr. Mukherjee attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set of continuous and discrete yarns (Ex. D at 2:40-41). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (Ex. D at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (Ex. D at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. V at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. D at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. E-G attached to my first report and CETR's images. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as

is shown by its product development (Ex. I at 68:25-70:15). The 446 Patent teaches “to tailor” the physical braid properties “by varying the type and proportion of each of the dissimilar fiber forming materials used” (Ex. D at 2:59-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. I at 68:25-70:15). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. D at 6:9-10).

Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can “*further*” improve the handleability of the suture (Ex. D at 6:5-18) (emphasis added). According to Dr. Mukherjee, FiberWire’s coating further improves handleability (Mukherjee Res. Report at 22-23). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. D at 6:11-13). As shown by the SEM’s of the FiberWire, the fibers are not bonded together (Mukherjee Res. Report at Ex. 20 and Exs. E-G). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

35. I further disagree with Dr. Mukherjee’s focus on FiberWire’s coating with reference to defining what is “material” because the 446 Patent is not about “coating” or eliminating “coatings.” Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. D at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (Ex. D at 1:32-43), a PTFE coating (Ex. D at 1:43-54), a monofilament like surface on a multifilament braid (Ex. D at 1:55-

3:2), and an elongated core (Ex. D at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (Ex. D at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

36. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties “attributable to the specific properties of the dissimilar fiber-forming materials” (Ex. D at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be “improved” by a coating (Ex. D at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent’s description of the invention shows that it does not consider coating, as used on FiberWire, to have a “material” effect on the basic and novel characteristics of the claimed suture.

3. To The Extent That I Understand Dr. Mukherjee’s Tests, They Are Irrelevant or Inconclusive

a) Dr. Mukherjee’s Tests Are Irrelevant

37. I note that Dr. Mukherjee opines that “coating materially affects handleability,” “knot security and knot strength” (Mukherjee Res. Report at 22 and 27). But he never opines on whether the coating materially affects the basic and novel characteristic that he attributes to the 446 Patent, namely two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. According to Dr.

Mukherjee, FiberWire's coating affects certain individual suture properties. But the novel and basic characteristics that he attributes are not just individual suture properties. Rather, they are the benefits of braiding dissimilar yarns to improve one property (*e.g.*, handleability) without significantly sacrificing others (*e.g.*, physical properties). As explained above, FiberWire's braided construction has these benefits. Accordingly, any purported affect by FiberWire's coating cannot be considered material in the context of the invention.

38. Dr. Mukherjee seems to rely on the 446 Patent's statement about preferred embodiments for his rationale that a coating will materially affect the basic and novel characteristics of the invention. But he misstates the statement upon which he relies and therefore incorrectly defines material effects. The 446 Patent states that "in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional *homogeneous* fiber braids, without sacrificing physical strength or knot security" (Ex. D at 2:62-66) (emphasis added). Thus, the 446 Patent was discussing improved properties relative to *homogeneous* braids, not relative to *uncoated heterogeneous* braids of dissimilar yarns. Dr. Mukherjee ignores the reference to the homogeneous braid.

b) Dr. Mukherjee's Testing and Analysis Is Flawed

39. Dr. Mukherjee relies on Pearsalls' knot strength data (Mukherjee Res. Report Ex. 25), testing performed by Arthrex (Mukherjee Res. Report Ex. 19), testing performed by CETR (Mukherjee Res. Report Ex. 20), and "drape tests" performed by him and Dr. Burke (Mukherjee Res. Report at 27). I do not have sufficient information to fully analyze all of these tests. For example, I do not have information sufficient to determine whether the only difference between the tested samples was coating, how the samples were manufactured, the parameters of the test specifications, and whether the reported data was the complete data obtained from any and all tests performed. Nevertheless, I have formed opinions to the extent that I can, based on the

limited information with which I have been provided. Also, I note that CETR and Dr. Mukherjee appear to have analyzed and tested only FiberWire size #2 and appear to have applied that analysis without any explanation to all FiberWire products.

(1) Pearsalls' Knot Pull Strength Tests Show No Material Change in Knot Pull Strength

40. Dr. Mukherjee relies on Pearsalls' knot pull strength data summarized in Exhibit 25 to his Responsive Report for his opinion that FiberWire's coating materially affects FiberWire's knot pull strength (Mukherjee Res. Report at 28-29). Exhibit 25 to Dr. Mukherjee's Responsive Report is a listing of the average knot pull strength per batch at the "dye" and "measure" stages. Dr. Mukherjee concludes from this data that the coating causes knot pull strength to materially increase. As I understand the data, the "dye" column is the average knot pull strength of a FiberWire batch that did not undergo the coating process that I observed at Pearsalls, and the "measure" column is the average knot pull strength of FiberWire that underwent the coating processes (Ex. U at 47; 1-23 Exs. Y and Z). This data appears to show that, in a significant number of instances, the measured knot pull strength *decreased* from the dye to the measure stage and therefore decreased after coating was applied to the suture. Also, at times, the measured knot pull strength stayed exactly the same. Thus, I do not know how Dr. Mukherjee can conclude from data, a significant amount of which is contradictory, that coating causes an increase in knot pull strength. He provides no explanation for this contradiction. Also, it is not clear why he necessarily attributes the change in knot pull strength to be due to coating. He fails to consider the inherent differences in tying knots, which can affect results, manufacturing differences between the "dye" and "measure" samples, and the known large variability in testing textile properties. Mr. Hallet from Pearsalls even explained that variations in the data, which Dr. Mukherjee relies upon, can be due to testing differences, not the material, and the variations in

the data were not really variations (Ex. U at 244:4-6; 348:22-349:6). To the extent that Dr. Mukherjee is relying on the final “average” computed in Ex. 25, that is improper.

41. I further disagree that Dr. Mukherjee can conclude from Pearsalls’ knot pull strength data that FiberWire’s coating materially affects FiberWire’s knot pull strength (Mukherjee Res. Report at 28-29) because he ignores entire sections of relevant data. Pearsalls’ normal practice is to perform knot pull strength testing at three stages of manufacturing, namely, the “dye,” “intermediate,” and “measure” stages. But Dr. Mukherjee wholly ignored the “intermediate” test stage data. The “intermediate” test stage data shows some of the flaws in his analysis. I understand that the suture that is tested during the “intermediate” and “measure” stage has not had any change in materials or undergone different processing (Ex. U at 348:5-13). Therefore, the knot pull strength should not change for a given batch between the “intermediate” and the “measure” stages. But, as summarized in Exhibit AA, Pearsalls’ testing shows that the measured knot pull strength was generally not the same at the intermediate and measure stages. Because Pearsalls measured “differences” in knot pull strength between the “intermediate” and “measure” stages, when one would have expected it to stay the same, it would not be correct to conclude that there was in fact a change in knot pull strength between the “intermediate” and “measure” stages. Likewise, absent some explanation, it is not correct to conclude that the knot pull strength is “changing” between the “dye” and “measure” stages. Rather, Pearsalls’ tests show that the knot pull strength basically stays the same before and after coating and that variations are probably due to testing differences, such as how the knot was tied. In fact, Mr. Hallet was asked why, for some batches, the average knot pull strength stayed about the same between the “dye” and “measure” stages, but went up at the “intermediate” stage (Ex. U at 341:16-344:25; Ex. BB). Mr. Hallet stated that the differences were probably due to the “operator” or the way the knot

was tied (Ex. U at 343:3-12). Also, Mr. Hallet testified that some changes were not really changes and were considered “about the same” (Ex. U at 344:22-25; Ex. CC). Further, when asked why, for one batch, the average knot pull strength went from 14.83 at the “intermediate” stage to “16.87” at the measure stage, Mr. Hallet attributed it to the “operator” (Ex. U at 346:21-347:1). Further, after reviewing the variations in some batches between the dye, intermediate, and measure stages, Mr. Hallet concluded that the data does not really show any variations in average knot pull strength:

Q Well, if you look at the testing you cannot really say -- are they all within the tolerance of the testing so that you cannot really say that one of these values is greater than the other?

A Yes.

MR. BONELLA: That's correct

A Yes.

(Ex. U at 348:22-349:6) (objection omitted). Thus, based on my review of Pearsalls' data and Mr. Hallet's explanation of the source of the data, I disagree with Dr. Mukherjee's opinion that he can conclude from the data in Exhibit 25 to his report that FiberWire's coating increased FiberWire's knot pull strength. If anything, Pearsalls' data show that FiberWire's coating has no material effect on knot pull strength.

(2) Arthrex's “Knot Tiedown” Test Is Inconclusive

42. With respect to Arthrex's “knot tiedown” test (Mukherjee Res. Report at Ex. 19), I am unable to draw any definitive conclusions from these tests because Dr. Mukherjee has not provided information about specifically which samples were tested. Also, with respect to Arthrex's “knot tiedown” test, I believe the test is not proper for the reasons expressed by Dr. Hermes.

(3) CETR's Tests Are Flawed and Inconclusive

43. Dr. Mukherjee relies on the CETR tests. But the CETR report does not explain what was tested other than “two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated.” Without further information about the construction, manufacturing, processing, and handling of the samples, I cannot completely comment on the CETR tests. Further, the testing methodology is not completely clear from the CETR report. Thus, I cannot fully comment on the tests that CETR conducted.

44. Even assuming that the only difference between the two tested samples is coating, the tests are also inconclusive for the following reasons. Dr. Mukherjee uses the CETR “pliability test” to determine the effect of coating on pliability. But the “pliability test” described in section 5 of the CETR report, and the data derived from this test, are flawed for at least three reasons: (i) the purported “pliability” test uses a *tensile* test to imply pliability; (ii) the “pliability” test incorrectly assumes that *multifilament* FiberWire acts as a *monofilament*; and (iii) the “pliability” assumes a circular cross-section and a constant diameter of the suture. I address each of these errors below.

45. The test described in section 5 of the CETR report is a *tensile* test in which the FiberWire samples were not bent; it is not a *bending* test. It is basic mechanical and textile engineering that tensile tests generally cannot be used to determine bending properties in and of themselves. Typically, a tensile test places a sample in tension by extending it to a given strain level and measuring the dependent variable, tension. In contrast, a typical bending test applies a bending moment to a specimen, measures the amount of deflection in response to the bending moment, and determines from this data a bending modulus or bending rigidity. A tensile test can be used to determine the bending modulus only in the unique circumstance when the material that makes up the specimen's tensile and compressive moduli are equal and the material is monolithic, such

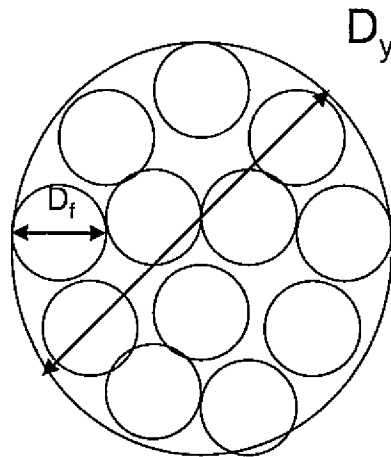
as certain monofilaments. By using a tensile test to determine bending rigidity, CETR assumes that coated FiberWire's tensile and compressive moduli are equal and uncoated FiberWire's tensile and compressive moduli are equal. Neither CETR nor Dr. Mukherjee provided any basis for this assumption. Without testing to prove that this assumption is correct or an explanation as to why it can be assumed, the "pliability" tests conducted by CETR are flawed.

46. The second reason the CETR "pliability" test is flawed is because it incorrectly assumes that *multifilament* FiberWire is a *monofilament*. CETR used the test method advanced in the Rodeheaver paper (Mukherjee Res. Report at Ex. 13) to determine FiberWire's pliability. But the mathematical relationship used by Rodeheaver to determine pliability assumes that the tested suture is a *monofilament* (Mukherjee Res. Report at Ex. 13 at 528). By assuming a monofilament structure, CETR simplistically assumes that a multifilament suture's pliability can be determined by measuring the tensile modulus, measuring suture diameter, and determining the moment of inertia of the suture. But FiberWire is a *multifilament* suture. To determine the bending rigidity of a multifilament textile structure, such as a suture, using the Rodeheaver equation is erroneous. It is well known in the textile field that a multifilament structure's bending rigidity is proportional to the number of filaments, the modulus of elasticity, the fiber-to-fiber mobility and *the individual moment of inertia of each filament*.⁴ In other words, the fiber-to-fiber mobility of the multifilament structure will affect the effective structural moment of inertia. Therefore, the Rodeheaver equation cannot be used to determine the pliability for FiberWire.

⁴ *Mechanics of Elastic Performance of Textile Materials, Part XIV: Some Aspects of Bending Rigidity of Singles Yarns*, Platt, M., Klein, W. and Hamburger, W., Textile Research Journal, August 1959 pp. 611-627 (Ex. DD).

47. To understand the errors in Dr. Mukherjee's analysis, consider three example structures and how their bending strength or pliability can be determined. First, consider a monofilament of constant material (and assuming an equal compressive and tensile moduli) and cross-sectional circular shape ("monofilament"). The Rodeheaver test is applicable to such a monofilament structure. Second, consider a multifilament which has total freedom of inter-fiber movement during bending ("multifilament"). Such a multifilament's bending properties can be understood with reference to the 1959 seminal paper by Platt, Klein and Hamburger (Ex. DD). As Platt et al. describe, for a multifilament having complete freedom of fiber movement the product of the bending modulus (E) and the moment of inertia (I) of a yarn is proportional to $N_f E_f I_f$ where N_f refers to the number of individual fibers, E_f refers to the individual fiber modulus, and I_f refers to the moment of inertia of an individual fiber. Third, consider a multifilament that does not have total freedom of inter-fiber movement during bending. The monofilament and multifilament (having complete fiber mobility) can be considered two extreme conditions with the multifilament not having complete freedom of fiber movement being between the other two conditions. Because FiberWire's structure is a braided multifilament, there cannot be complete freedom of fiber movement.

48. To understand the error in Dr. Mukherjee's analysis, I will contrast a hypothetical monofilament structure with a hypothetical multifilament with complete freedom of inter-fiber movement with reference to the Figure below (each multifilament acts independent of its neighboring filament).



Assume $4 \cdot D_f = D_y$. For a monofilament type structure, the moment of inertia would be $\pi D_y^4 / 64$, which is the equation used by CETR and originally advanced by Rodeheaver. But for a multifilament having 12 fibers and total freedom of movement, as shown in the picture, the moment of inertia is $12 \cdot \pi D_f^4 / 64$. Accordingly, the monofilament's and multifilament's moment of inertia, and therefore their bending rigidity, are not equal. Because FiberWire is neither a monofilament nor a multifilament having complete independent fiber movement, its bending stiffness is somewhere between a monofilament and multifilament structure. Thus, assuming FiberWire is a monofilament, as Dr. Mukherjee and the CETR testing assume, also produces errors.

49. The third reason that I disagree that Dr. Mukherjee can draw conclusions from CETR's "pliability tests" is that CETR incorrectly assumes that the FiberWire samples have a circular cross section and that the diameter of each FiberWire suture is constant and equal to 0.65 mm. (Mukherjee Res. Report at Ex. 20 at 3). The Rodeheaver paper assumes a constant circular cross section. Dr. Mukherjee and CETR do not provide any basis for the assumption that the FiberWire samples have a constant circular cross section. The Rodeheaver paper also assumes a

constant diameter along the linear axis of the tested structure. Dr. Mukherjee and CETR do not provide any basis for the assumption that the tested FiberWire samples have a constant diameter along their linear axis. I have consulted with Dr. Matt Hermes. Based on his experience, he opined that even amongst the same USP size suture, suture diameters vary along their linear axis. I have reviewed the attached summary of Pearsalls' batch records, and they show variation in FiberWire's diameter for sutures made from same batch (Ex. AA). For example, the suture diameter varies between the "dye" (uncoated) and "intermediate" (coated) stages, as well as between the "intermediate" and "measure" stages. Thus, FiberWire varies in diameter, and it was incorrect for Dr. Mukherjee and CETR to assume that it does not. This error in assuming that the diameter is always the same is magnified to the fourth power because, in the monofilament equation used by Dr. Mukherjee, the diameter of the suture is raised to the fourth power (Ex. 20 of Mukherjee Res. Report at 3).

50. I also note that CETR's "pliability test" graph is not an accurate depiction of the tensile stress-strain relationship. CETR uses a non-linear, non-logarithmic scale on the horizontal axis. This distorts the true slope of the data. Also, I am not sure whether CETR reported all of its data in this graph or a portion of the data. I note that the data reported seems to be only part of a stress-strain curve that is obtained from a typical tension test. I know this because Figure 2 does not show the strain to failure of either of the samples.

51. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by his "knot slippage strength tests" and "knot run-down tests." I have consulted with Dr. Hermes and, from what we know about these tests, they are basically a type of tension test, similar to the "pliability" test conducted by CETR. Therefore, the slope of the curve from these tests before slippage or run down should be similar to that

obtained in CETR's "pliability" test. But they are not. During the pliability tests, CETR found that the coated suture had a lower modulus, as shown by its smaller slope (Mukherjee Res. Report at Ex. 20 at 3-4). In contrast, the other two CETR tests report a higher modulus for the coated suture, but it is not clear by how much from the graph and data (Mukherjee Res. Report at Ex. 20 at 5-8). The point being that the tests results are inconsistent. They appear to contradict the conclusions drawn by Dr. Mukherjee from the CETR "pliability" tests. Based on the limited information that I have about the tests, they are either inconclusive or show that coating has no material affect on tensile strength because the variations are due to the testing, not the material.

52. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by Pearsalls' testing. Ex. AA summarizes the results of Pearsalls' tension tests on batches of FiberWire at the "dye," "intermediate," and "measure" stages. Pearsalls found that FiberWire's tensile strength basically stayed the same between the uncoated FiberWire and FiberWire that underwent the coating processes. Although there are some variations in the reported measurements (*i.e.*, the tensile strength appears to go up, down, and stay the same), it is my opinion that these are really just an artifact of the testing (*i.e.*, operator variations, knot tying, or the expected variations inherent to textile testing) and not true variations (see paragraphs 40-41). I note that Dr. Mukherjee ignores these data in his analysis.

(4) Dr. Mukherjee's "Drape" Test Is Flawed & Inconclusive

53. I have considered Dr. Mukherjee's "drape test." This "test" is overly simplistic and flawed. Dr. Mukherjee states that he performed his drape test by "draping the suture over [his] extended index finger and observing the degree to which the suture conforms to the shape of [his] finger" (Mukherjee Res. Report at 27). First, I do not understand what he means by "conforms to the shape of my finger." Therefore, I cannot fully respond to his statement

because, among other reasons, I cannot tell what he measured. Second, it appears that Dr. Mukherjee is attempting to approximate FiberWire's pliability by determining FiberWire's ability to bend by using his finger as a test rig. But this method is flawed because he did not provide a true cantilever end support. Consequently, there is no defined position as to where FiberWire begins its bending, and no definitive way to determine the degree of bending. Third, diameter affects pliability, and Dr. Mukherjee does not provide any diameter measurements for the samples that he compared. Therefore, based on what I can determine from his report, it is not possible to scientifically compare the pliability of the uncoated and coated FiberWire using this method.

54. I note that Dr. Mukherjee relies on documents that refer to Ethicon and Mitek products in his analysis (Mukherjee Res. Report at 23-24, Mukherjee Res. Report Exs. 14, 15, 17, & 18). I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products.

B. If Dr. Mukherjee Is Correct Regarding The Meaning Of The Novel And Basic Characteristics, TigerWire's Nylon Does Not Materially Affect Them

55. Dr. Mukherjee has opined that TigerWire does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 30). I disagree for the reasons stated above with respect to FiberWire.

56. I understand that the differences between TigerWire and FiberWire are that TigerWire is not dyed blue and replaces one PET yarn strand with one black nylon yarn strand. Dr. Mukherjee opines that TigerWire's nylon materially affects pliability (Mukherjee Res. Report at 30-31). I disagree. The purpose of the nylon strand is for visual identification (Ex. V at 74:21-23). It is my opinion that replacing one PET yarn with one nylon yarn does not materially affect

the novel and basic characteristics of the claimed suture because the nylon marker does not prevent or materially affect FiberWire's PET and UHMWPE from being dissimilar, from being braided, or from being braided to have improved handleability and pliability without significantly sacrificing physical properties. I note that Dr. Mukherjee does not opine otherwise. Rather, he seems to opine that the nylon marker affects pliability. He does not address the issue of whether FiberWire's braid of dissimilar yarns with improved handleability and pliability performance without significantly sacrificing physical properties is affected.

57. Dr. Mukherjee states that TigerWire's nylon yarn "make[s] TigerWire stiffer" than FiberWire, and "materially" affects "pliability" (Mukherjee Res. Report at 31). He also states that "nylon 6,6 fibers of the type used in TigerWire are generally more stiff (*i.e.* less pliable) than fibers made of PET, as used in FiberWire and TigerWire" (Mukherjee Res. Report at 30). I again disagree. First, I disagree that generally TigerWire's nylon 6,6 fibers are necessarily stiffer than PET fibers. Dr. Mukherjee cites to his Ex. 26 for the principle that nylon is stiffer than PET. But Ex. 26 shows the comparative characteristics of "unfilled" PET and "molding compound" nylon. These are not the characteristics of fibers made from these polymers. Thus, it is my opinion that it is improper, absent further information, to rely on this molding compound data for fiber properties. Even if it were proper to rely on this data, Ex. 26 shows that PET has a flexural modulus of 350,000 psi to 450,000 psi and that nylon 6,6 has a flexural modulus of 410,000 psi to 470,000 psi. There is a significant overlap in these ranges. Based on this data, it is possible that nylon 6,6 fibers and PET fibers used in FiberWire and TigerWire have substantially the same flexibility. In that instance, the substitution of one nylon fiber for one PET fiber would have no substantial effect on the pliability of the braid. Second, even if the nylon and PET yarns have different flexibility, but the flexibility were still in the range cited in

Ex. 26, it is my opinion that replacing one nylon yarn with one PET yarn would not materially affect the suture's pliability because the two types of material are close enough in flexural modulus as to be essentially indistinguishable in the FiberWire braid. In fact, the one nylon yarn only makes up about 12% of the suture by weight (Ex. EE at ARM 14744).

58. Dr. Mukherjee's opinion that nylon 66 is generally more stiff than polyester is contradicted by *Marks' Standard Handbook for Mechanical Engineers* (Ex. J at Table 2 at p. 6-155). The elastic modulus of nylon 66 fiber ranges from 25 to 50 gpd and the elastic modulus for polyester fiber, which I read to include polyester, ranges from 50-80 gpd. Thus, it is indicated that nylon 66 fiber is *less stiff* than polyester.

59. My opinion that TigerWire's nylon does not materially affect TigerWire's pliability is supported by Arthrex's testimony. My. Dreyfuss from Arthrex testified that TigerWire and FiberWire show "very similar" knot strength, tensile strength, [and] handleability (Ex. V at 76:1-5). Also, Mr. Dreyfuss testified that that the nylon strand had only "minute" effects on the feel of the suture as compared to FiberWire (Ex. V at 75:13).

60. I understand that Dr. Mukherjee relies on a "drape" test comparing FiberWire and TigerWire. My comments and opinions about Dr. Mukherjee's "drape" test above apply here as well. Additionally, I do not understand what Dr. Mukherjee means when he says "to a much greater degree" and the "course [sic] feel would suggest that the addition of the nylon would adversely affect knot tie-down" (Mukherjee Res. Report at 31). Therefore, I cannot really respond to his opinion. Nevertheless, I understand that Dr. Hermes has considered both no. 2 TigerWire and FiberWire. I also understand that he could not determine any significant difference in the stiffness of TigerWire and FiberWire. Again, Dr. Mukherjee provides no diameter measurements for the samples, and diameter can affect pliability.

C. If Dr. Mukherjee Is Correct Regarding The Meaning Of Novel And Basic Characteristics, The Adhesive As Used On Arthrex's FiberStick Product Does Not Materially Affect Them

61. Dr. Mukherjee has opined that FiberStick does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 31-32). I disagree for the reasons stated above with respect to FiberWire. Dr. Mukherjee also states that FiberStick's adhesive materially affects "suture" handleability and therefore concludes that the adhesive materially affects the novel and basic characteristics, as he defines them. It is not my opinion that the adhesive materially affects the novel and basic characteristics, as they are defined by Dr. Mukherjee, because about 38 inches of FiberWire does not have adhesive. The adhesive is irrelevant to the portion of FiberStick's that has no adhesive. Because the portion of FiberStick that has no adhesive still infringes, there is no reason to even consider the adhesive.

62. Arthrex's intended use of FiberStick confirms my opinion that the portion of FiberStick that has adhesive is irrelevant to the properties of the portion that has no adhesive. As I understand FiberStick, it is about a 50 inch length of FiberWire that has about 12 inches of its length treated with Loc-Tite (Ex. FF at ARM1495 at 13-2 and Ex. V at 122:1-15). According to FiberStick's design history file, a portion of FiberStick is treated to "allow for suture loading" and for suture passing through cannulated instruments (Ex. GG at ARM7847). Further, according to Arthrex's intended use, once FiberStick has been passed through a cannulated instrument, the portion having adhesive "can then be cut leaving the remaining suture in place to perform repairs" (Ex. GG at ARM7848). In fact, after the Loc-Tite treated portion of FiberStick has been cut and disposed of, Arthrex promotes using FiberStick's untreated "suture" portion in the "fashion identical to that which is currently marketed" (Ex. GG at ARM7850). The remaining suture is simply a FiberWire suture. As Arthrex states, the treated end does not "affect the design" of the suture (Ex. GG at ARM7848) or "change the intended use or

indication” (Ex. GG at ARM7850). The adhesive portion is only for suture placement; it does not affect the remainder of the suture. Thus, Arthrex’s intended use for FiberStick confirms my opinion that the adhesive has no material effect on the portion of FiberStick that does not have adhesive.

V. Reverse Doctrine of Equivalents

63. I have been asked to opine on the issue of whether the reverse doctrine of equivalents applies to FiberWire. Based on discussions with counsel, I understand that the reverse doctrine of equivalents applies when an accused product literally contains all the elements of a claim, but the product is so far changed in principle that it performs the function of the claimed invention in a substantially different way. It is my opinion that the reverse doctrine of equivalents does not apply because FiberWire is not so far changed in principle from the suture claimed in the 446 Patent. I disagree that FiberWire is so far changed in principle that it performs the function of the claimed invention in a substantially different way for the reasons explained above with reference to the doctrine of equivalents (*see* Section III).

VI. FiberWire’s Success Is Not Due To Just FiberWire’s UHMWPE

64. Dr. Mukherjee opines that he disagrees with my opinion that “some of the benefits marketed by Arthrex in selling FiberWire (and TigerWire) are due to the invention claimed in the ‘446 Patent” (Mukherjee Res. Report at 33). According to Dr. Mukherjee, the “superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE” (Mukherjee Res. Report at 34). I disagree with Dr. Mukherjee’s statement. Dr. Mukherjee’s statement is contradicted by Arthrex’s own marketing documents, technical documents, and technical witnesses.

65. I also disagree with Dr. Mukherjee because he ignores all of the benefits advanced by Arthrex in Arthrex’s marketing literature. For example, he ignores that Arthrex promotes that

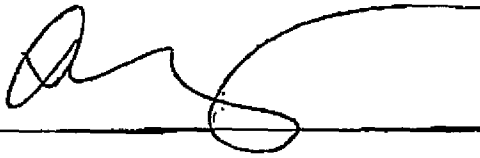
FiberWire's "polyester braided jacket . . . gives FiberWire superior strength" and it promotes FiberWire as a "braided polyblend suture" (Mukherjee Res. Report at Ex. 30). He further ignores that Arthrex touts other properties such as "knot slippage," knot profile" to name a few, which can be attributed to the claimed heterogeneous braid (Mukherjee Res. Report at Ex. 30) for the reasons provided below.

66. Mr. Grafton, developer of Arthrex's FiberWire, testified that the increase in strength of FiberWire is not due to UHMWPE. Mr. Grafton testified that a 100% UHMWPE braided suture was unacceptable because the knot holding strength was too low (Ex. I at 46:7-15; 52:16-20). Mr. Grafton said that the knot holding strength was too low because of the lubricity of the UHMWPE. Mr. Grafton then had the idea of adding PET into the braided structure, so that the PET would increase the knot holding strength (Ex. I at 53:8-11; 54:9-14). It was not until Arthrex braided the UHMWPE with PET that the "polyblend" suture became acceptable (Ex. I at 54:9-55:15).

67. Mr. Grafton also represented to the Patent Office that UHMWPE alone was not acceptable in suture applications because the knot tie down or knot security was too low (Ex. I at 24:18-21; 103:25-104:12; Ex. R). Based on these statements from Mr. Grafton, I disagree with Dr. Mukherjee when he states that "superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE." Rather, FiberWire's benefits touted by Arthrex can be attributed at least in part to the invention claimed in the 446 Patent.

68. I reserve the right to comment further on Dr. Mukherjee's analyses and report when more information about the analyses becomes available. I may use trial demonstratives to explain my opinions.

Dated: April 13, 2006

A handwritten signature in black ink, consisting of a stylized 'D' followed by a series of loops and a long horizontal stroke extending to the right.

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

CERTIFICATE OF SERVICE

I certify that the foregoing Rebuttal Expert Report of Dr. David Brookstein was served by Federal Express overnight mail on April 13, 2006 on the following:

Charles W. Saber
Dickstein, Shapiro, Morin & Oshinsky, LLP
2101 L. Street, NW
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Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109

Dated: April 13, 2006



Rich M. Falke

EXHIBIT 11

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Supplemental Expert Report of Dr. David Brookstein

I. Background Information

1. Based on new information presented to me since my last report, I submit this supplemental report. Additional information that I have reviewed in forming my opinions is attached as Exhibit II.

II. Summary of Opinions

2. The samples tested by Dr. Gitis that he labeled “coated” and “uncoated” were manufactured differently. These manufacturing differences affect FiberWire’s UHMWPE/PET braid. Therefore, it is my opinion that neither Dr. Gitis nor Dr. Mukherjee can make any scientifically reliable conclusions about the effect, if any, of FiberWire’s coating based on Dr. Gitis’ tests because they could not and did not determine what effects may be due to the coating and what effects may be due to the manufacturing differences between the samples (*e.g.*, the differences by which the UHMWPE/PET braids were made).

3. It is my opinion that Dr. Gitis' testing methodology was not based on accepted scientific methods or he failed to provide information that showed that his tests and analysis were based on accepted scientific methods. Therefore, it is my opinion that his tests and data cannot be relied on to analyze the effects, if any, of FiberWire's coating on the suture's properties.

4. It is my opinion that no reliable conclusions can be made about the effect, if any, of FiberWire's coating on the suture's properties based on Arthrex's knot tie-down test because either the "coated" or "uncoated" samples were manufactured differently or it is not known how they were manufactured.

III. Dr. Gitis' Tests Are Scientifically Unreliable Because The Tested Samples Differed In How They Were Manufactured

5. Dr. Gitis tested samples in which the only purported difference between the samples was that one set was "coated" and the other set was not. But the samples differed in more respects than just coating. Specifically, the "uncoated" sample was not heated and stretched, but the "coated" sample was heated and stretched twice, as is the case during the typical manufacturing of FiberWire sutures. Therefore, any conclusions that Dr. Mukherjee and Dr. Gitis made about the effect of a coating based on Dr. Gitis' tests are not reliable because they did not consider the whether the differences in properties, if any, were attributable to the stretching and/or heating.

6. My opinion is supported by the depositions of Mr. Hallett and Mr. Lewis in June 2006 and Pearsalls' manufacturing documents which show that the samples tested by Dr. Gitis were manufactured differently. I understand from counsel that Dr. Gitis tested FiberWire samples from Pearsalls batch 28893. Based on the deposition transcripts of Mr. Hallett and Mr. Lewis, I understand that the untreated FiberWire from batch 28893 that was used in Dr. Gitis' tests did not undergo the heating, stretching, and coating processes shown in Pearsalls' manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 17:18-21; 18:15-17; 24:2-8). In this report, I refer to

the “uncoated” samples tested by Dr. Gitis as the untreated samples because this is a more accurate description. I also understand that the treated FiberWire sample that Dr. Gitis used did undergo the heating, stretching, and coating processes shown in Pearsalls’ manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 27:10-25; Ex. LL at PR08466). I refer to the “coated” samples tested by Dr. Gitis as the treated samples.

7. Based on my January 2006 inspection of Pearsalls’ manufacturing operations and my review of their procedures, I understand Pearsalls’ processes used to manufacture FiberWire. During the inspection of the Pearsalls’ manufacturing facility, I personally witnessed the coating, heating, and stretching process used to make FiberWire. While at the inspection, I saw the stretching process. I saw exemplar pads that are tightened against the suture. The tightening of the pads against the suture provides a frictional force that must be overcome. This results in the suture being stretched as it is pulled at a rate of about 20 meters per minute. During my inspection, I plucked the FiberWire moving through the treating operations. Based on its resistance to transverse deformation, I observed that the FiberWire was under tension. I understand that Pearsalls refers to this manufacturing step as stretching (Ex. JJ; Ex. MM, Hallett Dep. at 32:12-14).

8. Based on my January 2006 inspection of Pearsalls’ manufacturing operations and my review of their procedures, I understand Pearsalls’ heat-treating process used to manufacture FiberWire. During my visit to Pearsalls’ facility, I also saw the equipment that is used for the heat-treating operations. I learned that the FiberWire sutures are processed by traversing the suture through a hot-air, four-stage convection oven while under tension. The suture threadline speed through the oven is generally 20 meters/minute and each stage of the four-stage oven was about 2 meters in length (Ex. MM, Hallett Dep. at 110:18-21). Accordingly, the suture

threadline has a residence time in each zone equal to about 6 seconds. Zones 1 and 2 are heated with hot air at 100°C (Ex. LL at PR8466). Zone 3 is heated with hot air at 130°C, and zone 4 is heated with hot air at 170°C (Ex. LL at PR8466). Thus, as the suture passes through the oven, the UHMWPE and PET braid is heated above 100°C but less than 170°C. The photographs that are attached to my expert report dated March 3, 2006 clearly show that the fibers have not fused or melted together.

9. It is my opinion that Pearsalls' heating and stretching processes affects FiberWire's properties. For example, it is my opinion that Pearsalls' heating and stretching processes will eliminate or reduce any minor bumps or irregularities along the suture surface, resulting in a smoother surface. This is described in the 446 Patent (Ex. D to my First Report at 5:61-6:1). Because heating and stretching affects surface properties, it affects the following suture properties: knot slippage, knot run-down, friction, chatter, and tissue drag. Since Dr. Gitis tested for these properties and Pearsalls' heating and stretching processes affect them, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire. My opinion is supported by the testimony of Dr. Mukherjee who testified that hot stretching processes affect a suture's strength and handling properties (Ex. NN, Mukherjee Dep. at 106:18-109:5; 110:2-4). Also, Pearsalls' heating and stretching processes affect pliability because they affect the moment of inertia, the modulus of the fibers, and the fiber-to-fiber interaction. Since Dr. Gitis tested for pliability and Pearsalls' heating and stretching affects pliability, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire.

10. Dr. Gitis tested untreated and treated FiberWire. As I understand his tests, he did not account for the stretching and heat-treating differences between the treated and untreated samples. Nor did Dr. Mukherjee account for these differences. Thus, they did not account for

whether the differences between the samples were due to differences between the heated and stretched UHMWPE/PET braid. Since the stretching and heat treating affects the properties for which Dr. Gitis was testing, it is not scientifically acceptable to attribute the differences in Dr. Gitis' results to only the coating on FiberWire.

IV. Dr. Gitis' Pliability Tests Are Scientifically Unreliable Because the Testing Methodology Is Either Flawed or Unexplained

A. Dr. Gitis' "Pliability" Test and Methodology Was Flawed

11. Dr. Gitis' "pliability" test is scientifically unacceptable because it is based on:

(1) stiffness data determined by a test using non-uniform loading rates; (2) flawed diameter measurements; (3) flawed assumptions about the moment of inertia, as discussed in my previous report (and not repeated here); and (4) unexplained methodology for calculating "stiffness."

1. Dr. Gitis' Pliability Tests Are Scientifically Unacceptable Because They Used Non-Uniform Loading Rates

12. Dr. Gitis used a tensile test to measure a parameter that he used to determine pliability. As I described in my Rebuttal Expert Report, I do not believe that this is an accurate methodology for testing FiberWire's pliability. But even if it were to be used, the testing methodology would have to be reliable. Here, it was not.

13. There are two accepted ways to perform a tensile test. One is a constant rate of extension test. For this test, a tensile specimen is secured between two jaws; one is stationary, and the other extends at a constant rate with regard to time. A load cell is also connected linearly to one of the jaws. The load cell measures the tensile force in the specimen, as it is being extended. Thus, the test yields data for plotting force vs. extension, and from this data the specimen's force vs. elongation behavior can be determined. It is my experience that this tensile testing method is the most commonly used and accepted tensile test by those who regularly perform tensile tests

on linear structures such as sutures. This test is described in ASTM D2256-02 “Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method” (Ex. OO).

14. The other accepted way to perform a tensile test is known as a constant rate of loading test. For this test, a tensile specimen is secured between two jaws with one being stationary and the other permitted to move such that the measured loads, which are also measured by a load cell, are increasing at a constant rate. This test is also described in ASTM D2256-02 “Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method” (Ex. OO).

15. For the constant rate of loading test, the loading rate must be the same because it is well known that fibers, such as those used in FiberWire, are materials having time-dependent, visco-elastic behavior. For these types of materials, it is scientifically unreliable to draw any conclusions by comparing the stress-strain relationship of specimens with different loading rates.

16. Dr. Gitis states in his report that the “pliability” tests were conducted by the constant rate of loading method. In that regard, he states in his report that the force was “uniformly increasing at the rate of 0.33 kg./sec.” I have examined the underlying data produced by Dr. Gitis and CETR. Based on my analysis of this data, the tests were not conducted as stated in Dr. Gitis’ report. Dr. Gitis used different loading rates on each sample. I used the TRENDLINE function incorporated in MS Excel software, on the modulus data in the Excel file provided to me, to determine the loading rate for each sample and the regression factor (R^2 , a measurement of the confidence between the actual data and curve or line which defines that data) and obtained the

following results:

	Untreated Sample Loading Rate, kg/sec	R ²	Treated Sample Loading Rate, kg/sec	R ²
1	0.094	0.9981	0.144	0.9984
2	0.060	0.9787	0.103	0.9931
3	0.074	0.9886	0.090	0.9947
4	0.050	0.9979	0.121	0.9988
5	0.036	0.9979	0.109	0.9968
6	0.073	0.9970	0.110	0.9890
7	0.053	0.9973	0.133	0.9905
8	0.058	0.9985	0.080	0.9925
Avg.	0.062		0.108	

As can be seen from this table, the load rates varied significantly between individual samples and even among the treated and untreated samples. In fact, the average loading rate for the untreated samples is approximately 75% greater than the average loading rate for the treated samples. Further, since the TRENDLINE function uses a linear relationship and the R² values are greater than the 95% accepted confidence level, the determined loading rates are accurate.

17. Consequently, no scientifically reliable “stiffness” conclusions can be drawn based on Dr. Gitis’ tests because the loading rate for each of the individual samples was not the same. Neither Dr. Gitis nor Dr. Mukherjee accounted for the differences in loading rate. Therefore, any conclusions that they drew from this data and the “stiffness” values reported by Dr. Gitis are neither reliable nor comparable. In fact, Dr. Gitis testified that if the sample load rates were different, it would “jeopardize the results” (Ex. PP, Gitis Dep. at 163:17).

2. Dr. Gitis’ Pliability Tests Are Scientifically Unreliable Because He Used the Wrong Diameter

18. In determining “stiffness,” Dr. Gitis assumed a monofilament circular structure. He also determined stiffness based on the moment of inertia, which is a function of the diameter raised to

the fourth power for a circular monofilament.¹ As I discussed in my previous report, I disagree with this assumption, but assuming that it is correct, it is important to use the correct diameters. This is because any error in the diameter between the treated and untreated samples results in an error in the “stiffness” values calculated by Dr. Gitis. It is my opinion that Dr. Gitis did not use accurate diameter measurements, and therefore, Dr. Gitis’ reported stiffness values are not scientifically acceptable.

19. I understand that Dr. Gitis used the same diameter for the treated and untreated FiberWire samples. That diameter was 0.65 mm (Gitis Report at 3). I understand from Dr. Gitis’ deposition that CETR measured the samples’ diameters with a caliper (Ex. PP, Gitis Dep. at 153:11-20). I am not able to fully review and analyze Dr. Gitis’ diameter measurements because he did record these measurements or the testing methodology (Ex. PP, Gitis Dep. at 174:7-10).

20. It is my opinion that Dr. Gitis’ measurements are inaccurate. Dr. Gitis’ diameter measurements contradict the measurements taken by Pearsalls. I have reviewed PR08456-57 (Ex. QQ). These documents show that Pearsalls measured the treated FiberWire’s average diameter as 0.586 mm and the untreated FiberWire’s average diameter as 0.600 mm. Therefore, Dr. Gitis’ measurements are different than Pearsalls’ measurements. In fact, Pearsalls measured the maximum diameter of the treated suture as 0.599 mm and the maximum diameter of the untreated suture as 0.635 mm., which are both less than the 0.65 mm diameter used by Dr. Gitis.

21. It is my opinion that Pearsalls uses a more accurate methodology for measuring diameter than Dr. Gitis. I understand that Pearsalls measures the diameter according to its TM36 procedure (Ex. JJ; Ex. RR; Ex. SS; Ex. TT, Hallett Dep. at 40:8-42:4; Ex. MM, Hallett Dep. at

¹ Dr. Gitis’ reported stiffness values also are dependent upon his assumption that the treated and untreated samples had a uniform circular cross-section. This not a correct assumption either.

174:12-20; 179:19-180:23; 185:4-9). Pearsalls' diameter measurement procedure (TM36) is stated to be performed according to the European pharmacopoeia (Ex. SS at PR8444). According to Pearsalls, the testing is accurate to 0.002 mm. (Ex. SS).

22. It is my opinion that Pearsalls' diameter measurement methodology is more accurate and scientifically reliable than using a caliper because it measures and keeps the transverse force constant. Dr. Gitis did not provide any information on whether he kept the transverse "crushing" force constant when he measured the sutures. Keeping the transverse "crushing" force constant is important because sutures are relatively compliant in transverse compression, indicating that they can deform during measurement and thereby yield inaccurate measurements. Because Dr. Gitis used a value (*i.e.*, 0.65 mm) that is higher than any valued measured by Pearsalls for the treated and untreated samples, obtained the same value for the treated and untreated samples, did not account for the "crushing" force, and used a caliper, it is my opinion that he did not use a scientifically reliable method for determining diameter.

3. The Stiffness Values Calculated By Dr. Gitis Were Not Performed With Scientifically Reliable Methods

23. Dr. Gitis purports to determine the stiffness values in Table 1 of his report by using the relationship between modulus of elasticity and moment of inertia. As I understand his methodology, Dr. Gitis determined the stiffness values according to the formula $(\text{slope}/(3.14 * D^2/4)) * D^4/64$. This is mathematically equivalent to $(\text{slope} * D^2)/16$. He used a diameter of 0.65 mm, and the slope was purportedly determined from the data he obtained from his tests.

24. His calculations are based on the determination of the slope of the force v. strain curves. I tried to reproduce his calculations but was not able to obtain the same results that he lists in Table 1. Dr. Gitis did not state in his report how he calculated the slope.

At deposition, Dr. Gitis testified that he calculated the slope of the curves by taking the change in force after the preload was set to the completion of the test, and divided that by the strain between after the preload was applied and the end of the test (Ex. PP, Gitis Dep. at 187:8-15). Although this is not a scientifically acceptable methodology, it will work if the data is a straight line or the best fit through the data is essentially linear. My review of the data indicates that it essentially follows a straight line relationship. Thus, I determined the slope and the stiffness values as Dr. Gitis states that he did, but I did not generate the same stiffness values (Ex. UU). This means that Dr. Gitis did not determine slope as he stated in his deposition. I do not know what methodology he used to determine slope.

25. I also tried to determine Dr. Gitis' stiffness values by fitting a best straight line through the data following the pre-load and determining the slope of that curve. This is a scientifically acceptable method for determining slope. I used the TRENDLINE function, which produces a linear regression analysis, incorporated in MS Excel software to determine the slope of each data set and the R^2 factor derived from each of the 16 sutures. I then multiplied each of the slope values by the diameter squared and divided it by 16, as Dr. Gitis suggested (Ex. PP, Gitis Dep. at 186:7-11).

The following table represents the pliability or stiffness for each of the 16 tested sutures using this method for determining slope.

	Treated, kg* m ²	R ²	Untreated, kg* m ²	R ²
1	8.71E-07	0.9974	7.50E-07	0.9936
2	3.74E-07	0.9883	7.23E-07	0.9983
3	6.17E-07	0.9936	9.17E-07	0.9980
4	3.58E-07	0.9915	7.49E-07	0.9955
5	2.81E-07	0.9904	5.35E-07	0.9831
6	4.28E-07	0.9891	1.00E-06	0.9766
7	3.99E-07	0.9984	1.04E-06	0.9958
8	3.40E-07	0.9906	8.24E-07	0.9976
Avg.	4.59E-07		8.18E-07	

As can be seen from this table, these pliability values are different than the ones reported in Dr. Gitis' report. Therefore, I do not understand what methodology Dr. Gitis used for determining slope and the "stiffness" values in Table 1 of his report. Because he has not shown what methodology he used, his methodology cannot be said to be scientifically acceptable.

26. I also note that Dr. Gitis' "pliability" test data details a parameter called "ZABS." I do not know what this parameter means, and Dr. Gitis was unable to explain what it means (Ex. PP, Gitis Dep. at 143:7-13). Thus, depending on what the parameter means, it may further affect my opinions.

B. No Reliable Conclusions About Pliability Can Be Drawn From Dr. Gitis' "Pliability" Test Because The Results Are Contradicted By Dr. Gitis' Tissue Drag Test

27. If the pliability test performed by Dr. Gitis is assumed to be reliable (it is my opinion that it is not) and the tissue drag test performed by Dr. Gitis is also assumed to be reliable (it is my opinion that it is not as described below), the "pliability" results from each test should be consistent. It is my opinion that the "pliability" results from each of these tests is not consistent and therefore no reliable conclusions about pliability can be drawn from Dr. Gitis' tests, even if

they were assumed to be proper tests. My analysis below assumes that the tissue drag test is a proper and reliable test. But it is not because the samples have differences other than coating, it incorrectly assumes a monofilament structure, it incorrectly assumes a circular cross section, it incorrectly assumes a constant diameter for all samples, and it assumes that the tissue-drag tests were done properly, which they were not.

28. The tissue drag test is described on page 12 of the CETR report. In the report, it is stated that a 20 mm length of suture was extended at a constant rate of 1 mm/sec while continuously recording the pulling force. Prior to the suture slipping, the test is similar to that specified in ASTM D2256-02 "Standard test method for tensile properties of yarn by the single strand method." Thus, putting aside the incorrect assumptions inherent in Dr. Gitis' tests and the flaws in the tissue drag tests (see below), prior to slipping between the leather pads, the recorded data can be used to determine the force/elongation relationship of the tested specimens.

29. I examined the data before slippage between the leather pads from the time period 0.1 to 0.5 seconds. This was to ensure that the time period of collected data was the same for each suture.

30. After examining the data, I plotted the individual force vs. strain data relationship for each of the eight coated and eight uncoated sutures. These plots are attached to this report as Ex. VV. I then used the TRENDLINE function incorporated in MS Excel software to determine the slope of each curve derived from each of the 16 sutures. These slopes represent the force on the thread line at a given time, or stated another way, force per unit time. Dr. Gitis reported that the specimens were originally 20 mm and the jaw moved at a constant rate of 1 mm/sec.

Accordingly, the strain rate on the specimen was 0.05 (mm/mm)/sec. I then divided the slope of each curve by 0.05/sec (the strain rate) and the assumed cross sectional area of each suture

(based on Dr. Gitis' assumed 0.65 mm) to obtain the tensile modulus. I then multiplied this value by the moment of inertia, based on Dr. Gitis' incorrect assumptions, to obtain the "pliability or stiffness" data for each suture. The following table represents the pliability or stiffness data for each of the 16 samples from the tissue drag test.

Specimen	Untreated, kg* m ²	R ²	Treated, kg* m ²	R ²
1	4.10E-07	0.9966	7.07E-07	0.9990
2	4.07E-07	0.9967	4.98E-07	0.9935
3	3.87E-07	0.9949	3.74E-07	0.9939
4	3.45E-07	0.9945	7.82E-07	0.9949
5	3.46E-07	0.9944	7.03E-07	0.9549
6	3.08E-07	0.9918	3.07E-07	0.9852
7	4.37E-07	0.9947	4.39E-07	0.9949
8	3.71E-07	0.9945	4.85E-07	0.9921
Avg.	3.76E-07		5.37E-07	

31. Based on this analysis, the tissue drag tests shows that the stiffness of the untreated suture was less than the stiffness of the treated suture. This contradicts what Dr. Gitis reported for his "pliability" test in Table 1 of his report where he reports that that the stiffness of the untreated suture was higher than the treated suture. Thus, even assuming his tests were done properly, no reliable conclusions can be drawn from them because the data from the tissue drag test contradicts the data from the "pliability" test.

V. Dr. Gitis' Knot Slippage Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

32. It is my opinion that Dr. Gitis did not determine the knot slippage strength using a scientifically reliable testing methodology. According to Dr. Gitis report, his methodology is described on page 5 of his report. He states that the parallel rods were pulled apart at a constant velocity of 1 mm/sec. While the rods were pulled, CETR personnel measured and recorded the force until either the knot untied or 3 mm of slippage occurred. However, the tests were not conducted as stated in his report.

33. I examined the underlying data of the knot slippage test and Dr. Gitis' deposition testimony. According to Dr. Gitis, the Z column in the knot slippage data is the vertical displacement of rods (Ex. PP, Gitis Dep. at 230:12-14). Consequently, if the test was performed at a constant velocity as stated in the test report, the Z value should increase 1 mm every second. However, the data does not show this. In fact, the data shows that the displacement decreases with increasing time. At deposition, Dr. Gitis testified that the data was not consistent with a constant velocity of 1 mm/sec. (Ex. PP, Gitis Dep. at 246:9-12). Further, Dr. Gitis was not able to explain why the data showed that the Z value decreased (Ex. PP, Gitis Dep. at 245:13-19). Also, he could not fully explain what the data in the F_x and F_y columns represented (Ex. PP, Gitis Dep. at 229:16-20). Therefore, the test was not performed as reported, and the data is not explained. Based on the information provided, the testing methodology is not a scientifically acceptable test because there is no adequate explanation of the test methods or the data. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot slippage strength values are just data without meaning and context, and they cannot be scientifically relied upon.

VI. Dr. Gitis' Knot Run-Down Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

34. It is my opinion that Dr. Gitis did not determine the knot run-down using a scientifically reliable test methodology. His methodology is partially described on page 7 of his report. However at deposition, Dr. Gitis could not fully describe the test methodology for this test. He testified that he did not know: (i) how the suture was attached to the upper brass rod (Ex. PP, Gitis Dep. at 236:3-9); and (ii) what he did with the lower end of the suture (Ex. PP, Gitis Dep. at 236:23-237:1). Dr. Gitis stated that he didn't remember how the test was conducted (Ex. PP, Gitis Dep. at 237:8-12). Thus, based on the information provided, the test, as described, is not a scientifically acceptable test because there is no adequate explanation of the test methods or how

the data was obtained. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot run-down values are just data without meaning and context, and they cannot be scientifically relied upon.

35. Although Dr. Gitis' knot-run down data is unreliable, even if were to be relied upon, it is inconclusive. Dr. Gitis' test results show in Table 3 that two of the treated samples had the same knot-run down force as two of the untreated samples. If coating has a material effect on knot run-down, then I do not understand why on two occasions the untreated samples had the same knot run-down force as two of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this (Ex. PP, Gitis Dep. at 218-226; Ex. WW, Mukherjee Dep. at 451:3-12). Absent an explanation, it is my further opinion that it is not scientifically reliable to conclude from the data that coating causes a smaller knot run-down force.

36. Also, I do not fully understand Dr. Gitis' knot run-down data because he could not explain it. He did not know what the data in the F_f column represented (Ex. PP, Gitis Dep. 241:10-11), and how the tests were conducted. Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

37. Further, I do not understand Dr. Gitis' methodology for reporting his data because the data he generated does not appear to correspond to the reported values in Table 3. For example, Dr. Gitis' data shows that coated sample 7 appeared to have the highest knot run-down peak force (Ex. XX, coated sample 7 denoted by blue unfilled circles). Yet, his reported data in Table 3 differs because coated sample 7 had a value of 0.19 kg., which was not the highest value reported in the chart. Dr. Gitis was not able to explain this difference (Ex. PP, Gitis Dep. at 242:16-243:4). Thus, I do not understand what methodology Dr. Gitis used, and his unknown methodology cannot be considered reliable.

VII. Dr. Gitis' Friction Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

38. Dr. Gitis' friction tests are scientifically unreliable because the testing methodology was flawed, and there was no explanation of how the coefficient of friction was determined. Dr. Gitis' report partially describes the friction tests on page 9. According to Dr. Gitis, two sutures were each held in a suture holder by clamping one suture end and holding the other suture end by tightening a screw against the suture (Ex. PP, Gitis Dep. at 249:4-21). Dr. Gitis did not measure the clamping force (Ex. PP, Gitis Dep. at 249:22-24). Further, he did not measure the torque on the screw or the force placed on the suture by the screw (Ex. PP, Gitis Dep. at 249:25-250:2). Nor did he accurately control how tight the screw was placed against the suture (Ex. PP, Gitis Dep. at 250:16-252:9). Because Dr. Gitis' friction tests relies on rubbing two sutures against each other, the tension under which the sutures are subject to in the holder affects the measured friction parameters. Because Dr. Gitis did not use a scientifically reliable method to check the tension on the sutures in the suture holders, no scientific reliable conclusions can be drawn based on his friction tests.

39. Based on the information that was provided, Dr. Gitis' friction test methodology is also not scientifically reliable because he could not explain how his testing machine and software determined the coefficient of friction (Ex. PP, Gitis Dep. at 261:10-14; 263:14-265:6). Absent an explanation of how the friction coefficients were determined, they are values without any meaning, and they cannot be scientifically relied upon to determine the coefficient of friction.

40. Also, I do not fully understand Dr. Gitis' friction data because he could not explain it. He did not know what the F_f represented (Ex. PP, Gitis Dep. at 261:1-9). Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

VIII. Dr. Gitis' Chatter Data Is Unreliable Because the Testing Methodology Is Not Known

41. It is my opinion that Dr. Gitis' chatter data on page 11 of his report is not scientifically reliable because no explanation was provided as to how it was determined. Dr. Gitis provides a brief explanation on page 11 of his report but does not explain specifically how it was determined (*i.e.* he does not explain what "maximum and minimum" amplitudes were used and how they were used to generate the results from the friction and knot run-down tests). At his deposition, he was not able to explain how the chatter values were determined (Ex. PP, Gitis Dep. at 268:1-269:5). Therefore, absent an explanation of how the chatter values were determined, they are just values without any meaning, and they cannot be scientifically relied upon to draw conclusions.

42. Also, it appears that certain data related to Dr. Gitis' chatter determinations were not maintained by Dr. Gitis (Ex. PP, Gitis Dep. at 267:10-23). Since I did not have the opportunity to review the data, I cannot use it to understand whether Dr. Gitis used a scientifically acceptable method.

43. Further, Dr. Gitis' tests also show that one of the treated samples had about the same chatter value (0.012) as at least four of the untreated samples (0.013, 0.013, 0.012, 0.011), and another of the treated samples (0.010) had a value that was the same as at least one of the untreated samples (0.011). If coating had a material effect on chatter, then I do not understand why some of the untreated samples had the same chatter value as some of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this discrepancy (Ex. PP, Gitis Dep. at 269:22-270:2; Ex. WW, Mukherjee Dep. at 464:21-465:4). Based on these results, it is my further opinion that it is not scientifically reliable to conclude from the data that coating materially affects FiberWire's chatter.

IX. Dr. Gitis' Tissue Drag Data Is Unreliable Because the Testing Methodology Is Flawed

44. Dr. Gitis' tissue drag test involved dragging a suture through two pieces of leather that were clamped together. The results of the tissue drag test are a function of how tight the leather was clamped against the suture. If the force applied to the suture by the leather differed between samples, this will lead to different results that cannot be compared. Dr. Gitis clamped the leather together with a nut and bolt (Ex. PP, Gitis Dep. at 272:24-273:1). But Dr. Gitis did not control the force that was applied to the leather or how tightly the sutures were clamped between the leather (Ex. PP, Gitis Dep. at 273:2-5). Thus, because Dr. Gitis did not control the clamping force, he did not use a scientifically reliable methodology for performing the tissue-drag test, and it is not scientifically acceptable to compare the data he obtained between samples.

45. I also note that Dr. Gitis states in his report at page 12 that he conducted a second different tissue drag test with a needle. He did not provide any data or results from this test in his report or subsequent to his report. I understand that he no longer has the data (Ex. PP, Gitis Dep. at 271:10-272:9). Thus, I have not been provided the opportunity to assess this test or its results. It could be that this test contradicts his other tests, but I do not know because I have not seen the data.

46. Also, I note that Dr. Gitis' tissue drag data does not seem to correlate with his reported data. For example, his data shows that untreated sample 5 (magenta) had the highest static tissue-drag force (Ex. YY). But his report in table 6 shows that the highest static tissue-drag force for the untreated samples was sample no. 4. Dr. Gitis was not able to explain this discrepancy (Ex. PP, Gitis Dep. at 279:11-280:5). Thus, it is not clear what methodology Dr. Gitis used to obtain his reported tissue drag values. Therefore, for this additional reason, his unknown methodology cannot be considered scientifically reliable.

X. Arthrex's Knot-Down Test Is Scientifically Unreliable For Assessing The Effects of FiberWire's Coating on FiberWire's Properties

47. Dr. Mukherjee also relies on a "knot-tie down" test performed by Arthrex (Ex. 19 to Dr. Mukherjee's Responsive Report, see Mukherjee's Responsive Report at 24-25), which purportedly shows the effects of FiberWire's coating on knot tie-down properties. I am not aware of any documentation that establishes the construction and manufacturing processes that were used to construct the "uncoated" suture used in this test. Therefore, absent information about the construction and manufacturing of the tested samples, it is not possible to say that the only difference between the samples was coating. Further, it is scientifically unreliable to attribute the differences in the test results to coating.

48. I understand that Arthrex's counsel has indicated that the samples produced as ARM 25452 (DM Ex. 430) may be uncoated sutures from the same batch as that used in Arthrex's knot tie-down test. The sample designated as ARM25452 is white and does not have FiberWire's blue dye. I note that Mr. Grafton's email from July 2004 indicates that the "uncoated" samples used in Arthrex's knot-run down test were "removed from production before dying and coating" (Ex. ZZ). The sample and Mr. Grafton's email suggest that the untreated samples used in Arthrex's knot tie down test was not dyed, scoured, coated, stretched, or heated. Therefore, even if the sample known as ARM 25452 is the type that was tested by Arthrex, there is no scientific reliable method for making any conclusions about the materiality of the affects of FiberWire's coating on FiberWire's properties.

XI. The FiberWire Photos Provided in Dr. Gitis' Report Do Not Show Coating

49. Based on the information provided about the pictures shown in Dr. Gitis' report it, I cannot determine whether they show any coating. My opinion is supported by Dr. Gitis who stated that he could not see coating when he observed the samples under magnification (Ex. PP,

Gitis Dep. at 285:9-14). I understand that Dr. Mukherjee has opined that Figure 14 in Dr. Gitis' report shows coated sutures because the fibers are allegedly spaced closer together (Ex. WW, Mukherjee Dep. at 461:23-462:10). It is my opinion that this is not a scientifically acceptable analysis or conclusion. I understand from Dr. Gitis' and Dr. Mukherjee's testimony that it is not known what part of FiberWire is shown in the photos, and it is not known how exactly the material shown was handled (Ex. WW, Mukherjee Dep. at 462:12-18; Ex. PP, Gitis Dep. at 289:8-16). Thus, the spacing between the fibers could be a function of how the sutures were handled, cut, or clamped during the photos, as described by Dr. Gitis (Ex. PP, Gitis Dep. at 288:12-20). There is no reliable methodology provided by Dr. Mukherjee for opining that Figure 14 shows coating. I note that Dr. Gitis had other pictures taken but did not provide them for analysis (Ex. PP, Gitis Dep. at 286:7-17).

XII. Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material

50. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. AAA, Burks' Dep. at 87:7-13; 88:1-3; 96:18-19; 98:19-25). He also stated that he could not "clearly feel a difference" (Ex. AAA, Burks Dep. at 88:9-10). This supports my opinion that any purported differences are not material.

51. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (Ex. AAA, Burks Dep. at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (Ex. AAA, Burks Dep. at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (Ex. AAA, Burks. Dep. at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in

surgery (Ex. AAA, Burks Dep. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

Dated: July 14, 2006

A handwritten signature in black ink, consisting of a large, stylized 'D' followed by a series of loops and a long horizontal stroke extending to the right.

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers


CERTIFICATE OF SERVICE

I certify that the foregoing Supplemental Expert Report of Dr. David Brookstein was served in the manner indicated below on July 14, 2006 on the following:

*Via e-mail without exhibits and
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Dated: July 14, 2006



Erich M. Falke

EXHIBIT 12

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Amended Supplemental Expert Report of Dr. David Brookstein

I. Background Information

1. Based on new information presented to me since my last report, I submit this supplemental report. Additional information that I have reviewed in forming my opinions is attached as Exhibit II.

II. Summary of Opinions

2. The samples tested by Dr. Gitis that he labeled “coated” and “uncoated” were manufactured differently. These manufacturing differences affect FiberWire’s UHMWPE/PET braid. Therefore, it is my opinion that neither Dr. Gitis nor Dr. Mukherjee can make any scientifically reliable conclusions about the effect, if any, of FiberWire’s coating based on Dr. Gitis’ tests because they could not and did not determine what effects may be due to the coating and what effects may be due to the manufacturing differences between the samples (*e.g.*, the differences by which the UHMWPE/PET braids were made).

3. It is my opinion that Dr. Gitis' testing methodology was not based on accepted scientific methods or he failed to provide information that showed that his tests and analysis were based on accepted scientific methods. Therefore, it is my opinion that his tests and data cannot be relied on to analyze the effects, if any, of FiberWire's coating on the suture's properties.

4. It is my opinion that no reliable conclusions can be made about the effect, if any, of FiberWire's coating on the suture's properties based on Arthrex's knot tie-down test because either the "coated" or "uncoated" samples were manufactured differently or it is not known how they were manufactured.

III. Dr. Gitis' Tests Are Scientifically Unreliable Because The Tested Samples Differed In How They Were Manufactured

5. Dr. Gitis tested samples in which the only purported difference between the samples was that one set was "coated" and the other set was not. But the samples differed in more respects than just coating. Specifically, the "uncoated" sample was not heated and stretched, but the "coated" sample was heated and stretched twice, as is the case during the typical manufacturing of FiberWire sutures. Therefore, any conclusions that Dr. Mukherjee and Dr. Gitis made about the effect of a coating based on Dr. Gitis' tests are not reliable because they did not consider the whether the differences in properties, if any, were attributable to the stretching and/or heating.

6. My opinion is supported by the depositions of Mr. Hallett and Mr. Lewis in June 2006 and Pearsalls' manufacturing documents which show that the samples tested by Dr. Gitis were manufactured differently. I understand from counsel that Dr. Gitis tested FiberWire samples from Pearsalls batch 28893. Based on the deposition transcripts of Mr. Hallett and Mr. Lewis, I understand that the untreated FiberWire from batch 28893 that was used in Dr. Gitis' tests did not undergo the heating, stretching, and coating processes shown in Pearsalls' manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 17:18-21; 18:15-17; 24:2-8). In this report, I refer to

the “uncoated” samples tested by Dr. Gitis as the untreated samples because this is a more accurate description. I also understand that the treated FiberWire sample that Dr. Gitis used did undergo the heating, stretching, and coating processes shown in Pearsalls’ manufacturing flowchart (Ex. JJ) (Ex. KK, Lewis Dep. at 27:10-25; Ex. LL at PR08466). I refer to the “coated” samples tested by Dr. Gitis as the treated samples.

7. Based on my January 2006 inspection of Pearsalls’ manufacturing operations and my review of their procedures, I understand Pearsalls’ processes used to manufacture FiberWire. During the inspection of the Pearsalls’ manufacturing facility, I personally witnessed the coating, heating, and stretching process used to make FiberWire. While at the inspection, I saw the stretching process. I saw exemplar pads that are tightened against the suture. The tightening of the pads against the suture provides a frictional force that must be overcome. This results in the suture being stretched as it is pulled at a rate of about 20 meters per minute. During my inspection, I plucked the FiberWire moving through the treating operations. Based on its resistance to transverse deformation, I observed that the FiberWire was under tension. I understand that Pearsalls refers to this manufacturing step as stretching (Ex. JJ; Ex. MM, Hallett Dep. at 32:12-14).

8. Based on my January 2006 inspection of Pearsalls’ manufacturing operations and my review of their procedures, I understand Pearsalls’ heat-treating process used to manufacture FiberWire. During my visit to Pearsalls’ facility, I also saw the equipment that is used for the heat-treating operations. I learned that the FiberWire sutures are processed by traversing the suture through a hot-air, four-stage convection oven while under tension. The suture threadline speed through the oven is generally 20 meters/minute and each stage of the four-stage oven was about 2 meters in length (Ex. MM, Hallett Dep. at 110:18-21). Accordingly, the suture

threadline has a residence time in each zone equal to about 6 seconds. Zones 1 and 2 are heated with hot air at 100°C (Ex. LL at PR8466). Zone 3 is heated with hot air at 130°C, and zone 4 is heated with hot air at 170°C (Ex. LL at PR8466). Thus, as the suture passes through the oven, the UHMWPE and PET braid is heated above 100°C but less than 170°C. The photographs that are attached to my expert report dated March 3, 2006 clearly show that the fibers have not fused or melted together.

9. It is my opinion that Pearsalls' heating and stretching processes affects FiberWire's properties. For example, it is my opinion that Pearsalls' heating and stretching processes will eliminate or reduce any minor bumps or irregularities along the suture surface, resulting in a smoother surface. This is described in the 446 Patent (Ex. D to my First Report at 5:61-6:1). Because heating and stretching affects surface properties, it affects the following suture properties: knot slippage, knot run-down, friction, chatter, and tissue drag. Since Dr. Gitis tested for these properties and Pearsalls' heating and stretching processes affect them, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire. My opinion is supported by the testimony of Dr. Mukherjee who testified that hot stretching processes affect a suture's strength and handling properties (Ex. NN, Mukherjee Dep. at 106:18-109:5; 110:2-4). Also, Pearsalls' heating and stretching processes affect pliability because they affect the moment of inertia, the modulus of the fibers, and the fiber-to-fiber interaction. Since Dr. Gitis tested for pliability and Pearsalls' heating and stretching affects pliability, it is my opinion that any differences that he found cannot be attributed to only the coating on FiberWire.

10. Dr. Gitis tested untreated and treated FiberWire. As I understand his tests, he did not account for the stretching and heat-treating differences between the treated and untreated samples. Nor did Dr. Mukherjee account for these differences. Thus, they did not account for

whether the differences between the samples were due to differences between the heated and stretched UHMWPE/PET braid. Since the stretching and heat treating affects the properties for which Dr. Gitis was testing, it is not scientifically acceptable to attribute the differences in Dr. Gitis' results to only the coating on FiberWire.

IV. Dr. Gitis' Pliability Tests Are Scientifically Unreliable Because the Testing Methodology Is Either Flawed or Unexplained

A. Dr. Gitis' "Pliability" Test and Methodology Was Flawed

11. Dr. Gitis' "pliability" test is scientifically unacceptable because it is based on:

(1) stiffness data determined by a test using non-uniform loading rates; (2) flawed diameter measurements; (3) flawed assumptions about the moment of inertia, as discussed in my previous report (and not repeated here); and (4) unexplained methodology for calculating "stiffness."

1. Dr. Gitis' Pliability Tests Are Scientifically Unacceptable Because They Used Non-Uniform Loading Rates

12. Dr. Gitis used a tensile test to measure a parameter that he used to determine pliability. As I described in my Rebuttal Expert Report, I do not believe that this is an accurate methodology for testing FiberWire's pliability. But even if it were to be used, the testing methodology would have to be reliable. Here, it was not.

13. There are two accepted ways to perform a tensile test. One is a constant rate of extension test. For this test, a tensile specimen is secured between two jaws; one is stationary, and the other extends at a constant rate with regard to time. A load cell is also connected linearly to one of the jaws. The load cell measures the tensile force in the specimen, as it is being extended. Thus, the test yields data for plotting force vs. extension, and from this data the specimen's force vs. elongation behavior can be determined. It is my experience that this tensile testing method is the most commonly used and accepted tensile test by those who regularly perform tensile tests

on linear structures such as sutures. This test is described in ASTM D2256-02 “Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method” (Ex. OO).

14. The other accepted way to perform a tensile test is known as a constant rate of loading test. For this test, a tensile specimen is secured between two jaws with one being stationary and the other permitted to move such that the measured loads, which are also measured by a load cell, are increasing at a constant rate. This test is also described in ASTM D2256-02 “Standard Test Method For Tensile Properties Of Yarns By The Single Strand Method” (Ex. OO).

15. For the constant rate of loading test, the loading rate must be the same because it is well known that fibers, such as those used in FiberWire, are materials having time-dependent, visco-elastic behavior. For these types of materials, it is scientifically unreliable to draw any conclusions by comparing the stress-strain relationship of specimens with different loading rates.

16. Dr. Gitis states in his report that the “pliability” tests were conducted by the constant rate of loading method. In that regard, he states in his report that the force was “uniformly increasing at the rate of 0.33 kg./sec.” I have examined the underlying data produced by Dr. Gitis and CETR. Based on my analysis of this data, the tests were not conducted as stated in Dr. Gitis’ report. Dr. Gitis used different loading rates on each sample. I used the TRENDLINE function incorporated in MS Excel software, on the modulus data in the Excel file provided to me, to determine the loading rate for each sample and the regression factor (R^2 , a measurement of the confidence between the actual data and curve or line which defines that data) and obtained the

following results:

	Treated Sample Loading Rate, kg/sec	R ²	Untreated Sample Loading Rate, kg/sec	R ²
1	0.094	0.9981	0.144	0.9984
2	0.060	0.9787	0.103	0.9931
3	0.074	0.9886	0.090	0.9947
4	0.050	0.9979	0.121	0.9988
5	0.036	0.9979	0.109	0.9968
6	0.073	0.9970	0.110	0.9890
7	0.053	0.9973	0.133	0.9905
8	0.058	0.9985	0.080	0.9925
Avg.	0.062		0.108	

As can be seen from this table, the load rates varied significantly between individual samples and even among the treated and untreated samples. In fact, the average loading rate for the untreated samples is approximately 75% greater than the average loading rate for the treated samples. Further, since the TRENDLINE function uses a linear relationship and the R² values are greater than the 95% accepted confidence level, the determined loading rates are accurate.

17. Consequently, no scientifically reliable “stiffness” conclusions can be drawn based on Dr. Gitis’ tests because the loading rate for each of the individual samples was not the same. Neither Dr. Gitis nor Dr. Mukherjee accounted for the differences in loading rate. Therefore, any conclusions that they drew from this data and the “stiffness” values reported by Dr. Gitis are neither reliable nor comparable. In fact, Dr. Gitis testified that if the sample load rates were different, it would “jeopardize the results” (Ex. PP, Gitis Dep. at 163:17).

2. Dr. Gitis’ Pliability Tests Are Scientifically Unreliable Because He Used the Wrong Diameter

18. In determining “stiffness,” Dr. Gitis assumed a monofilament circular structure. He also determined stiffness based on the moment of inertia, which is a function of the diameter raised to

the fourth power for a circular monofilament.¹ As I discussed in my previous report, I disagree with this assumption, but assuming that it is correct, it is important to use the correct diameters. This is because any error in the diameter between the treated and untreated samples results in an error in the “stiffness” values calculated by Dr. Gitis. It is my opinion that Dr. Gitis did not use accurate diameter measurements, and therefore, Dr. Gitis’ reported stiffness values are not scientifically acceptable.

19. I understand that Dr. Gitis used the same diameter for the treated and untreated FiberWire samples. That diameter was 0.65 mm (Gitis Report at 3). I understand from Dr. Gitis’ deposition that CETR measured the samples’ diameters with a caliper (Ex. PP, Gitis Dep. at 153:11-20). I am not able to fully review and analyze Dr. Gitis’ diameter measurements because he did record these measurements or the testing methodology (Ex. PP, Gitis Dep. at 174:7-10).

20. It is my opinion that Dr. Gitis’ measurements are inaccurate. Dr. Gitis’ diameter measurements contradict the measurements taken by Pearsalls. I have reviewed PR08456-57 (Ex. QQ). These documents show that Pearsalls measured the treated FiberWire’s average diameter as 0.586 mm and the untreated FiberWire’s average diameter as 0.600 mm. Therefore, Dr. Gitis’ measurements are different than Pearsalls’ measurements. In fact, Pearsalls measured the maximum diameter of the treated suture as 0.599 mm and the maximum diameter of the untreated suture as 0.635 mm., which are both less than the 0.65 mm diameter used by Dr. Gitis.

21. It is my opinion that Pearsalls uses a more accurate methodology for measuring diameter than Dr. Gitis. I understand that Pearsalls measures the diameter according to its TM36 procedure (Ex. JJ; Ex. RR; Ex. SS; Ex. TT, Hallett Dep. at 40:8-42:4; Ex. MM, Hallett Dep. at

¹ Dr. Gitis’ reported stiffness values also are dependent upon his assumption that the treated and untreated samples had a uniform circular cross-section. This not a correct assumption either.

174:12-20; 179:19-180:23; 185:4-9). Pearsalls' diameter measurement procedure (TM36) is stated to be performed according to the European pharmacopoeia (Ex. SS at PR8444). According to Pearsalls, the testing is accurate to 0.002 mm. (Ex. SS).

22. It is my opinion that Pearsalls' diameter measurement methodology is more accurate and scientifically reliable than using a caliper because it measures and keeps the transverse force constant. Dr. Gitis did not provide any information on whether he kept the transverse "crushing" force constant when he measured the sutures. Keeping the transverse "crushing" force constant is important because sutures are relatively compliant in transverse compression, indicating that they can deform during measurement and thereby yield inaccurate measurements. Because Dr. Gitis used a value (*i.e.*, 0.65 mm) that is higher than any valued measured by Pearsalls for the treated and untreated samples, obtained the same value for the treated and untreated samples, did not account for the "crushing" force, and used a caliper, it is my opinion that he did not use a scientifically reliable method for determining diameter.

3. The Stiffness Values Calculated By Dr. Gitis Were Not Performed With Scientifically Reliable Methods

23. Dr. Gitis purports to determine the stiffness values in Table 1 of his report by using the relationship between modulus of elasticity and moment of inertia. As I understand his methodology, Dr. Gitis determined the stiffness values according to the formula $(\text{slope}/(3.14 * D^2/4)) * D^4/64$. This is mathematically equivalent to $(\text{slope} * D^2)/16$. He used a diameter of 0.65 mm, and the slope was purportedly determined from the data he obtained from his tests.

24. His calculations are based on the determination of the slope of the force v. strain curves. I tried to reproduce his calculations but was not able to obtain the same results that he lists in Table 1. Dr. Gitis did not state in his report how he calculated the slope.

At deposition, Dr. Gitis testified that he calculated the slope of the curves by taking the change in force after the preload was set to the completion of the test, and divided that by the strain between after the preload was applied and the end of the test (Ex. PP, Gitis Dep. at 187:8-15). Although this is not a scientifically acceptable methodology, it will work if the data is a straight line or the best fit through the data is essentially linear. My review of the data indicates that it essentially follows a straight line relationship. Thus, I determined the slope and the stiffness values as Dr. Gitis states that he did, but I did not generate the same stiffness values (Ex. UU). This means that Dr. Gitis did not determine slope as he stated in his deposition. I do not know what methodology he used to determine slope.

25. I also tried to determine Dr. Gitis' stiffness values by fitting a best straight line through the data following the pre-load and determining the slope of that curve. This is a scientifically acceptable method for determining slope. I used the TRENDLINE function, which produces a linear regression analysis, incorporated in MS Excel software to determine the slope of each data set and the R^2 factor derived from each of the 16 sutures. I then multiplied each of the slope values by the diameter squared and divided it by 16, as Dr. Gitis suggested (Ex. PP, Gitis Dep. at 186:7-11).

The following table represents the pliability or stiffness for each of the 16 tested sutures using this method for determining slope.

	Treated, kg* m ²	R ²	Untreated, kg* m ²	R ²
1	8.71E-07	0.9974	7.50E-07	0.9936
2	3.74E-07	0.9883	7.23E-07	0.9983
3	6.17E-07	0.9936	9.17E-07	0.9980
4	3.58E-07	0.9915	7.49E-07	0.9955
5	2.81E-07	0.9904	5.35E-07	0.9831
6	4.28E-07	0.9891	1.00E-06	0.9766
7	3.99E-07	0.9984	1.04E-06	0.9958
8	3.40E-07	0.9906	8.24E-07	0.9976
Avg.	4.59E-07		8.18E-07	

As can be seen from this table, these pliability values are different than the ones reported in Dr. Gitis' report. Therefore, I do not understand what methodology Dr. Gitis used for determining slope and the "stiffness" values in Table 1 of his report. Because he has not shown what methodology he used, his methodology cannot be said to be scientifically acceptable.

26. I also note that Dr. Gitis' "pliability" test data details a parameter called "ZABS." I do not know what this parameter means, and Dr. Gitis was unable to explain what it means (Ex. PP, Gitis Dep. at 143:7-13). Thus, depending on what the parameter means, it may further affect my opinions.

B. No Reliable Conclusions About Pliability Can Be Drawn From Dr. Gitis' "Pliability" Test Because The Results Are Contradicted By Dr. Gitis' Tissue Drag Test

27. If the pliability test performed by Dr. Gitis is assumed to be reliable (it is my opinion that it is not) and the tissue drag test performed by Dr. Gitis is also assumed to be reliable (it is my opinion that it is not as described below), the "pliability" results from each test should be consistent. It is my opinion that the "pliability" results from each of these tests is not consistent and therefore no reliable conclusions about pliability can be drawn from Dr. Gitis' tests, even if

they were assumed to be proper tests. My analysis below assumes that the tissue drag test is a proper and reliable test. But it is not because the samples have differences other than coating, it incorrectly assumes a monofilament structure, it incorrectly assumes a circular cross section, it incorrectly assumes a constant diameter for all samples, and it assumes that the tissue-drag tests were done properly, which they were not.

28. The tissue drag test is described on page 12 of the CETR report. In the report, it is stated that a 20 mm length of suture was extended at a constant rate of 1 mm/sec while continuously recording the pulling force. Prior to the suture slipping, the test is similar to that specified in ASTM D2256-02 "Standard test method for tensile properties of yarn by the single strand method." Thus, putting aside the incorrect assumptions inherent in Dr. Gitis' tests and the flaws in the tissue drag tests (see below), prior to slipping between the leather pads, the recorded data can be used to determine the force/elongation relationship of the tested specimens.

29. I examined the data before slippage between the leather pads from the time period 0.1 to 0.5 seconds. This was to ensure that the time period of collected data was the same for each suture.

30. After examining the data, I plotted the individual force vs. strain data relationship for each of the eight coated and eight uncoated sutures. These plots are attached to this report as Ex. VV. I then used the TRENDLINE function incorporated in MS Excel software to determine the slope of each curve derived from each of the 16 sutures. These slopes represent the force on the thread line at a given time, or stated another way, force per unit time. Dr. Gitis reported that the specimens were originally 20 mm and the jaw moved at a constant rate of 1 mm/sec.

Accordingly, the strain rate on the specimen was 0.05 (mm/mm)/sec. I then divided the slope of each curve by 0.05/sec (the strain rate) and the assumed cross sectional area of each suture

(based on Dr. Gitis' assumed 0.65 mm) to obtain the tensile modulus. I then multiplied this value by the moment of inertia, based on Dr. Gitis' incorrect assumptions, to obtain the "pliability or stiffness" data for each suture. The following table represents the pliability or stiffness data for each of the 16 samples from the tissue drag test.

Specimen	Untreated, kg* m ²	R ²	Treated, kg* m ²	R ²
1	4.10E-07	0.9966	7.07E-07	0.9990
2	4.07E-07	0.9967	4.98E-07	0.9935
3	3.87E-07	0.9949	3.74E-07	0.9939
4	3.45E-07	0.9945	7.82E-07	0.9949
5	3.46E-07	0.9944	7.03E-07	0.9549
6	3.08E-07	0.9918	3.07E-07	0.9852
7	4.37E-07	0.9947	4.39E-07	0.9949
8	3.71E-07	0.9945	4.85E-07	0.9921
Avg.	3.76E-07		5.37E-07	

31. Based on this analysis, the tissue drag tests shows that the stiffness of the untreated suture was less than the stiffness of the treated suture. This contradicts what Dr. Gitis reported for his "pliability" test in Table 1 of his report where he reports that that the stiffness of the untreated suture was higher than the treated suture. Thus, even assuming his tests were done properly, no reliable conclusions can be drawn from them because the data from the tissue drag test contradicts the data from the "pliability" test.

V. Dr. Gitis' Knot Slippage Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

32. It is my opinion that Dr. Gitis did not determine the knot slippage strength using a scientifically reliable testing methodology. According to Dr. Gitis report, his methodology is described on page 5 of his report. He states that the parallel rods were pulled apart at a constant velocity of 1 mm/sec. While the rods were pulled, CETR personnel measured and recorded the force until either the knot untied or 3 mm of slippage occurred. However, the tests were not conducted as stated in his report.

33. I examined the underlying data of the knot slippage test and Dr. Gitis' deposition testimony. According to Dr. Gitis, the Z column in the knot slippage data is the vertical displacement of rods (Ex. PP, Gitis Dep. at 230:12-14). Consequently, if the test was performed at a constant velocity as stated in the test report, the Z value should increase 1 mm every second. However, the data does not show this. In fact, the data shows that the displacement decreases with increasing time. At deposition, Dr. Gitis testified that the data was not consistent with a constant velocity of 1 mm/sec. (Ex. PP, Gitis Dep. at 246:9-12). Further, Dr. Gitis was not able to explain why the data showed that the Z value decreased (Ex. PP, Gitis Dep. at 245:13-19). Also, he could not fully explain what the data in the F_x and F_y columns represented (Ex. PP, Gitis Dep. at 229:16-20). Therefore, the test was not performed as reported, and the data is not explained. Based on the information provided, the testing methodology is not a scientifically acceptable test because there is no adequate explanation of the test methods or the data. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot slippage strength values are just data without meaning and context, and they cannot be scientifically relied upon.

VI. Dr. Gitis' Knot Run-Down Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

34. It is my opinion that Dr. Gitis did not determine the knot run-down using a scientifically reliable test methodology. His methodology is partially described on page 7 of his report. However at deposition, Dr. Gitis could not fully describe the test methodology for this test. He testified that he did not know: (i) how the suture was attached to the upper brass rod (Ex. PP, Gitis Dep. at 236:3-9); and (ii) what he did with the lower end of the suture (Ex. PP, Gitis Dep. at 236:23-237:1). Dr. Gitis stated that he didn't remember how the test was conducted (Ex. PP, Gitis Dep. at 237:8-12). Thus, based on the information provided, the test, as described, is not a scientifically acceptable test because there is no adequate explanation of the test methods or how

the data was obtained. Absent a complete explanation of how the test was conducted, Dr. Gitis' knot run-down values are just data without meaning and context, and they cannot be scientifically relied upon.

35. Although Dr. Gitis' knot-run down data is unreliable, even if were to be relied upon, it is inconclusive. Dr. Gitis' test results show in Table 3 that two of the treated samples had the same knot-run down force as two of the untreated samples. If coating has a material effect on knot run-down, then I do not understand why on two occasions the untreated samples had the same knot run-down force as two of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this (Ex. PP, Gitis Dep. at 218-226; Ex. WW, Mukherjee Dep. at 451:3-12). Absent an explanation, it is my further opinion that it is not scientifically reliable to conclude from the data that coating causes a smaller knot run-down force.

36. Also, I do not fully understand Dr. Gitis' knot run-down data because he could not explain it. He did not know what the data in the F_f column represented (Ex. PP, Gitis Dep. 241:10-11), and how the tests were conducted. Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

37. Further, I do not understand Dr. Gitis' methodology for reporting his data because the data he generated does not appear to correspond to the reported values in Table 3. For example, Dr. Gitis' data shows that coated sample 7 appeared to have the highest knot run-down peak force (Ex. XX, coated sample 7 denoted by blue unfilled circles). Yet, his reported data in Table 3 differs because coated sample 7 had a value of 0.19 kg., which was not the highest value reported in the chart. Dr. Gitis was not able to explain this difference (Ex. PP, Gitis Dep. at 242:16-243:4). Thus, I do not understand what methodology Dr. Gitis used, and his unknown methodology cannot be considered reliable.

VII. Dr. Gitis' Friction Tests Are Unreliable Because the Testing Methodology Is Either Flawed or Not Explained

38. Dr. Gitis' friction tests are scientifically unreliable because the testing methodology was flawed, and there was no explanation of how the coefficient of friction was determined. Dr. Gitis' report partially describes the friction tests on page 9. According to Dr. Gitis, two sutures were each held in a suture holder by clamping one suture end and holding the other suture end by tightening a screw against the suture (Ex. PP, Gitis Dep. at 249:4-21). Dr. Gitis did not measure the clamping force (Ex. PP, Gitis Dep. at 249:22-24). Further, he did not measure the torque on the screw or the force placed on the suture by the screw (Ex. PP, Gitis Dep. at 249:25-250:2). Nor did he accurately control how tight the screw was placed against the suture (Ex. PP, Gitis Dep. at 250:16-252:9). Because Dr. Gitis' friction tests relies on rubbing two sutures against each other, the tension under which the sutures are subject to in the holder affects the measured friction parameters. Because Dr. Gitis did not use a scientifically reliable method to check the tension on the sutures in the suture holders, no scientific reliable conclusions can be drawn based on his friction tests.

39. Based on the information that was provided, Dr. Gitis' friction test methodology is also not scientifically reliable because he could not explain how his testing machine and software determined the coefficient of friction (Ex. PP, Gitis Dep. at 261:10-14; 263:14-265:6). Absent an explanation of how the friction coefficients were determined, they are values without any meaning, and they cannot be scientifically relied upon to determine the coefficient of friction.

40. Also, I do not fully understand Dr. Gitis' friction data because he could not explain it. He did not know what the F_f represented (Ex. PP, Gitis Dep. at 261:1-9). Thus, I do not fully understand Dr. Gitis' data and tests because he could not explain the data.

VIII. Dr. Gitis' Chatter Data Is Unreliable Because the Testing Methodology Is Not Known

41. It is my opinion that Dr. Gitis' chatter data on page 11 of his report is not scientifically reliable because no explanation was provided as to how it was determined. Dr. Gitis provides a brief explanation on page 11 of his report but does not explain specifically how it was determined (*i.e.* he does not explain what "maximum and minimum" amplitudes were used and how they were used to generate the results from the friction and knot run-down tests). At his deposition, he was not able to explain how the chatter values were determined (Ex. PP, Gitis Dep. at 268:1-269:5). Therefore, absent an explanation of how the chatter values were determined, they are just values without any meaning, and they cannot be scientifically relied upon to draw conclusions.

42. Also, it appears that certain data related to Dr. Gitis' chatter determinations were not maintained by Dr. Gitis (Ex. PP, Gitis Dep. at 267:10-23). Since I did not have the opportunity to review the data, I cannot use it to understand whether Dr. Gitis used a scientifically acceptable method.

43. Further, Dr. Gitis' tests also show that one of the treated samples had about the same chatter value (0.012) as at least four of the untreated samples (0.013, 0.013, 0.012, 0.011), and another of the treated samples (0.010) had a value that was the same as at least one of the untreated samples (0.011). If coating had a material effect on chatter, then I do not understand why some of the untreated samples had the same chatter value as some of the treated samples. Neither Dr. Gitis nor Dr. Mukherjee was able to explain this discrepancy (Ex. PP, Gitis Dep. at 269:22-270:2; Ex. WW, Mukherjee Dep. at 464:21-465:4). Based on these results, it is my further opinion that it is not scientifically reliable to conclude from the data that coating materially affects FiberWire's chatter.

IX. Dr. Gitis' Tissue Drag Data Is Unreliable Because the Testing Methodology Is Flawed

44. Dr. Gitis' tissue drag test involved dragging a suture through two pieces of leather that were clamped together. The results of the tissue drag test are a function of how tight the leather was clamped against the suture. If the force applied to the suture by the leather differed between samples, this will lead to different results that cannot be compared. Dr. Gitis clamped the leather together with a nut and bolt (Ex. PP, Gitis Dep. at 272:24-273:1). But Dr. Gitis did not control the force that was applied to the leather or how tightly the sutures were clamped between the leather (Ex. PP, Gitis Dep. at 273:2-5). Thus, because Dr. Gitis did not control the clamping force, he did not use a scientifically reliable methodology for performing the tissue-drag test, and it is not scientifically acceptable to compare the data he obtained between samples.

45. I also note that Dr. Gitis states in his report at page 12 that he conducted a second different tissue drag test with a needle. He did not provide any data or results from this test in his report or subsequent to his report. I understand that he no longer has the data (Ex. PP, Gitis Dep. at 271:10-272:9). Thus, I have not been provided the opportunity to assess this test or its results. It could be that this test contradicts his other tests, but I do not know because I have not seen the data.

46. Also, I note that Dr. Gitis' tissue drag data does not seem to correlate with his reported data. For example, his data shows that untreated sample 5 (magenta) had the highest static tissue-drag force (Ex. YY). But his report in table 6 shows that the highest static tissue-drag force for the untreated samples was sample no. 4. Dr. Gitis was not able to explain this discrepancy (Ex. PP, Gitis Dep. at 279:11-280:5). Thus, it is not clear what methodology Dr. Gitis used to obtain his reported tissue drag values. Therefore, for this additional reason, his unknown methodology cannot be considered scientifically reliable.

X. Arthrex's Knot-Down Test Is Scientifically Unreliable For Assessing The Effects of FiberWire's Coating on FiberWire's Properties

47. Dr. Mukherjee also relies on a "knot-tie down" test performed by Arthrex (Ex. 19 to Dr. Mukherjee's Responsive Report, see Mukherjee's Responsive Report at 24-25), which purportedly shows the effects of FiberWire's coating on knot tie-down properties. I am not aware of any documentation that establishes the construction and manufacturing processes that were used to construct the "uncoated" suture used in this test. Therefore, absent information about the construction and manufacturing of the tested samples, it is not possible to say that the only difference between the samples was coating. Further, it is scientifically unreliable to attribute the differences in the test results to coating.

48. I understand that Arthrex's counsel has indicated that the samples produced as ARM 25452 (DM Ex. 430) may be uncoated sutures from the same batch as that used in Arthrex's knot tie-down test. The sample designated as ARM25452 is white and does not have FiberWire's blue dye. I note that Mr. Grafton's email from July 2004 indicates that the "uncoated" samples used in Arthrex's knot-run down test were "removed from production before dying and coating" (Ex. ZZ). The sample and Mr. Grafton's email suggest that the untreated samples used in Arthrex's knot tie down test was not dyed, scoured, coated, stretched, or heated. Therefore, even if the sample known as ARM 25452 is the type that was tested by Arthrex, there is no scientific reliable method for making any conclusions about the materiality of the affects of FiberWire's coating on FiberWire's properties.

XI. The FiberWire Photos Provided in Dr. Gitis' Report Do Not Show Coating

49. Based on the information provided about the pictures shown in Dr. Gitis' report it, I cannot determine whether they show any coating. My opinion is supported by Dr. Gitis who stated that he could not see coating when he observed the samples under magnification (Ex. PP,

Gitis Dep. at 285:9-14). I understand that Dr. Mukherjee has opined that Figure 14 in Dr. Gitis' report shows coated sutures because the fibers are allegedly spaced closer together (Ex. WW, Mukherjee Dep. at 461:23-462:10). It is my opinion that this is not a scientifically acceptable analysis or conclusion. I understand from Dr. Gitis' and Dr. Mukherjee's testimony that it is not known what part of FiberWire is shown in the photos, and it is not known how exactly the material shown was handled (Ex. WW, Mukherjee Dep. at 462:12-18; Ex. PP, Gitis Dep. at 289:8-16). Thus, the spacing between the fibers could be a function of how the sutures were handled, cut, or clamped during the photos, as described by Dr. Gitis (Ex. PP, Gitis Dep. at 288:12-20). There is no reliable methodology provided by Dr. Mukherjee for opining that Figure 14 shows coating. I note that Dr. Gitis had other pictures taken but did not provide them for analysis (Ex. PP, Gitis Dep. at 286:7-17).


XII. Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material

50. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. AAA, Burks' Dep. at 87:7-13; 88:1-3; 96:18-19; 98:19-25). He also stated that he could not "clearly feel a difference" (Ex. AAA, Burks Dep. at 88:9-10). This supports my opinion that any purported differences are not material.

51. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (Ex. AAA, Burks Dep. at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (Ex. AAA, Burks Dep. at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (Ex. AAA, Burks. Dep. at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in

surgery (Ex. AAA, Burks Dep. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

Dated: July 24, 2006

A handwritten signature in black ink, appearing to read 'David Brookstein', is written over a horizontal line.

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

CERTIFICATE OF SERVICE

I certify that the foregoing Amended Supplemental Expert Report of Dr. David Brookstein was served in the manner indicated below on July 24, 2006 on the following:

*Via e-mail without exhibits and
via Federal Express delivery (without exhibits)*
Charles W. Saber
Dickstein Shapiro LLP
1825 Eye Street NW
Washington D.C. 20006-5403
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Via Federal Express
Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109

Dated: July 24, 2006



Erich M. Falke

Amended List of Additional Materials Considered

Deposition Transcript of Mr. Lewis with exhibits
Deposition Transcript of Mr. Hallet from June 30, 2006 with exhibits
Steven B. Warner, *Fiber Science* 1995
Deposition Transcript of Dr. Gitis with exhibits
Deposition Transcript of Dr. Mukherjee with exhibits
CETR Testing data
Pearsalls documents 008433-008473
CETR documents 0001-79
FiberWire Samples Ex. 388, 390, 438, 429, 389, 428, 235, 236, 237
Dr. Burks Transcript with exhibits
“An Experimental Method for Determining the heat Transfer Coefficient of Polymeric Fibers and Yarns During Rapid Convective heating” by R. Brooks published in The Journal of the Textile Institute 1984, No. 6, I then pp. 398-404.
DM. Ex 430
DM. Ex. 433
DM. Ex. 434
ARM25591
PR08325-08382
TestWorks®4 “Continuing to set the standard for material, component, and subassembly testing software”
Gordon Laboratory Seminar Series Lent 2006
ASTM International, Designation: D 638-03, “Standard Test Method for Tensile Properties of Plastics”

EXHIBIT 13

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Expert Report of Dr. David Brookstein

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

B. Work Experience

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

C. Publications

6. My publications include, among other things:

"Joining Methods of Advanced Braided Composites," Composite Structures, 6, p. 87-95, 1986.

"Structural Applications of Advanced Braided Composites," Proceedings of the SPE Advanced Polymers Composites Division, November 1988.

"Processing Advanced Braided Composite Structures," Proceedings of the WAM of ASME, Materials Division, November 1988.

"Interlocked Fiber Architecture: Braided and Woven," Proceedings of the 35th SAMPE Meeting, April, 1990.

"Evolution of Fabric Preforms for Composites," Journal of Applied Polymer Science: Applied Polymer Symposium, 47, p. 487-500, 1991.

"A Comparison of Multilayer Interlocked Braided Composites with Other 3-D Braided Composites," 3rd International Techtextil Symposium, 14-16, May 1991, Frankfurt.

"On the Mechanical Behavior of 3-D Multilayer Interlock Braided Composites," with Preller, T., and Brandt, J., DASA-Deutsche Aerospace, Proceedings of NASA Fiber-Tex '92.

"The Solid Section Multilayer Interlock Braiding System," 4th International Techtextil Symposium, 4 June 1992, Frankfurt.

"On the Mechanical Properties of Three-Dimensional Multilayer Interlock Braided Composites," TECHTEXTIL Symposium, 1993, Frankfurt.

"3-D Braided Composites-Design and Applications," Sixth European Conference on Composite Materials, 20-24 September 1993, Bordeaux.

"Concurrent Engineering of 3-D Textile Preforms for Composites," International Journal of Materials and Product Technology, Vol. 9, Nos. 1/2/3, 1994.

"Physical Properties of Twisted Structures" with Ning Pan, Fiber Society Symposium, Asheville, NC, 1998.

D. Patents

7. I am an inventor on the following U.S. Patents:

U.S. Patent 4,290,170 - "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.

U.S. Patent 4,497,866 - "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.

U.S. Patent 4,602,892 - "Sucker Rod," A braided composite rod and coupling for pumping oil.

U.S. Patent 4,841,613 - "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.

U.S. Patent 4,909,127 - "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.

U.S. Patent 5,004,474 - "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.

U.S. Patent 5,357,839 - "Solid Braid Structure" A 3-D system for producing braids.

U.S. Patent 5,358,758 - "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.

U.S. Patent 5,411,463 - "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.

U.S. Patent 5,501,133 - "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.

U.S. Patent 5,697,969 - "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

E. Education

8. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

9. I have a Master of Science in Textile Technology from M.I.T., 1973.

10. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

11. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

12. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based, resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

13. A copy of my CV is attached under Tab A. A list of my publications and patents are set forth in my CV. Over the past four years, I have been deposed or testified as an Expert Witness in five cases. A complete list of cases in which I have provided testimony within the past four years is attached under Tab B. A list of the documents that I used in forming my opinions is set forth in Tab C.

14. I have been engaged by counsel of DePuy Mitek as a consultant in this litigation at a consulting rate of \$300/hour.

II. Summary of Opinions

15. It is my opinion that sales of Arthrex's FiberWire™ and TigerWire™ suture products (in all sizes and regardless of whether it is attached to needle, or any other component)

literally infringe claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 (the '446 Patent) (Tab D). I understand that Arthrex sells FiberWire™ in the United States as free strands, attached to needles of various sizes, and attached to anchors used in various surgical applications (*e.g.*, rotator cuff repair, shoulder instability procedures). I further understand that Arthrex sells TigerWire™ in the United States attached to needles and anchors. I use the term "FiberWire™ suture products" to refer to all FiberWire™ products regardless of whether they are free strands, attached to needles, or attached to anchors. I use the term "TigerWire™ suture products" to refer to all TigerWire™ products regardless of whether they are sold attached to anchors or needles.

16. It is my opinion that sale of Arthrex's FiberWire™ and TigerWire™ suture products (in all suture sizes) directly infringes claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents.

17. I understand that Pearsalls imports into, and sells in, the United States unsterile, untipped FiberWire™ and TigerWire™. It is my opinion that such unsterile, untipped products are a component of the invention claimed in the '446 patent and constitute a material part of the invention claimed in claims 1, 2, 8, 9, and 12 of the '446 patent.

18. It is my opinion that the FiberWire™ and TigerWire™ sutures imported and sold by Pearsalls are especially adapted for use in infringement of claims 1, 2, 8, 9, and 12 of the 446 Patent, and are not a staple article or commodity of commerce suitable for substantial noninfringing use.

19. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ sutures are due to the invention, claimed in claims 1, 2, 8, 9, and 12 of the 446 Patent.

III. Materials Considered in Forming My Opinions

20. I understand that Arthrex has admitted that Pearsalls manufactures the Arthrex FiberWire™ and TigerWire™ suture. (Arthrex's Response to Mitek Interrogatory #2). I

attended the Pearsalls plant inspection and deposition in Taunton, Somerset, England on January 11, 2006. Mr. Brian Hallet testified on behalf of Pearsalls. While attending the Pearsalls plant inspection, I personally observed the manufacturing processes used to make the braid that comprises the FiberWire™ and TigerWire™ sutures. I may testify about the manufacturing process that I observed on January 11, 2006 at Pearsalls and the explanation of it as set forth by Pearsalls at depositions and in documents. I may use videotape deposition testimony or exhibits made from the videotape to aid me in testifying.

21. The manufacturing process to make the FiberWire™ and TigerWire™ suture braids that I observed includes the following steps: twisting core and sheath yarns, steam setting core and sheath, winding braider bobbins, braiding, winding to skein, scouring, dyeing, stretching, coating, and thermal treating, and subsequent inspection. I also observed Pearsall's testing laboratory. I may testify about each of these processes and the Pearsalls' equipment used in the manufacturing and testing processes. In addition to observing the manufacturing processes, I have also reviewed documents that describe them (DMI Exs. 279, 281, 287-312). I may rely on these documents in testifying about FiberWire™ and TigerWire™.

22. I have reviewed technical documents concerning FiberWire™'s and TigerWire™'s construction and manufacturing. I have also reviewed deposition transcripts of technical witnesses concerning FiberWire™ and TigerWire™, including the depositions of, among others, Arthrex Engineer, Peter Dreyfuss, Arthrex's Vice President of Operations Kevin Grief, and Pearsalls' Brian Hallet. A list of the documents that I used in forming my opinions is set forth in Tab C.

23. I have examined samples of FiberWire™ and samples of FiberWire™ taken at various stages of the manufacturing processes (DMI Exs. 282, 283, 284, 285, 342 and Bates nos. ARM 25451-52, and ARM 25590).

IV. Legal Framework of My Opinions

I have been told by counsel to apply the following principles of United States Patent law in my analysis.

A. Direct Infringement

24. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

25. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

26. Infringement is “literal” when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still infringement if the device has an equivalent of the claimed limitation that is not literally present. I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused

device “performs substantially the same function in substantially the same way to obtain the same result” (“function/way/result test”) as the claimed element.

V. Direct Infringement

A. Claim Construction

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the ‘446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

“PE” – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

“consisting essentially of” – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

“direct intertwining contact” –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

“volume fraction of the first set of yarns in the braided sheath and core” means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions provided by counsel.

B. Literal Infringement

28. I have been asked to provide my expert opinion regarding whether Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my opinion that Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my understanding that Arthrex has offered for sale or sold each of its FiberWire™ and TigerWire™ suture products within the United States. Therefore, there is literal infringement because, as described below, each of Arthrex's FiberWire™ and TigerWire™ suture products literally has all of the limitations of claims 1, 2, 8, 9, and 12. In determining literal infringement, I first consider the construction of FiberWire™ and TigerWire™. Then, I compare the claims, with the definitions as provided above, to the FiberWire™ and TigerWire™ suture products.

1. Arthrex's FiberWire™ and TigerWire™ Suture Products

29. I understand that all Arthrex's FiberWire™ suture, except size 4-0, is made of a core of polyethylene yarns (of the ultra high molecular weight type) and a braided sheath of polyethylene yarns (of the ultra high molecular weight type) and PET yarns (Dreyfuss 9/16/05 Dep. at 43, 55-57). The braided sheath is made by having one set of carriers, which have polyethylene, traversing the braider bed in a serpentine and clockwise fashion and the other set of carriers, which have PET, traversing the braider bed in a serpentine counter-clockwise fashion. I understand that Arthrex sells only sizes 5, 2, 0, 2-0, 3-0, and 4-0 FiberWire™ (Dreyfuss 9/16/05 Dep. at 31). I understand that the description of FiberWire™ is generally described in Arthrex's 510K for FiberWire™ (DMI Ex. 78 at ARM 001899).

30. I also understand that no. 2 Arthrex TigerWire™ is basically identical to no. 2 FiberWire™ with one exception. TigerWire™ has one black nylon yarn that replaces one of the PET yarns in no. 2 FiberWire™. No. 2 TigerWire™ has 8 yarns of PE, 7 yarns of PET, and 1 yarn of nylon braided together. (DMI Ex. 318) I also understand that Arthrex sells TigerWire™ in only size no. 2 (Dreyfuss 9/16/05 Dep. at 106). I understand that Arthrex also sells a TigerTail™¹ product that “is a version of FiberWire™ suture with a black strand that creates spiral marking along one-half length of the suture” (DMI Ex. 318).

31. I understand that FiberWire™ and TigerWire™ have been made with “Spectra” and “Dyneema” ultra high molecular weight polyethylene yarns in manufacturing the FiberWire™ suture (Dreyfuss Dep. p. 44-45, Grieff Dep. 9/15/05 p. 22-23, and 51). Spectra and Dyneema are trade names for certain companies’ ultra high molecular weight polyethylene.

32. Arthrex’s FiberWire™ and TigerWire™ suture is coated with NuSil Med-2174 manufactured by NuSil technology. (Dreyfuss 9/16/05 Dep. at 42). NuSil MED-2174 is generally described at DMI Ex. 78 at ARM 1933-36. I also understand that Arthrex sells a FiberStick™² product. I understand FiberStick™ to be a 50 inch piece of FiberWire™ that has 12 inches of its length stiffened with Loc-Tite (DMI Ex. 3 and Dreyfuss 9/16/05 Dep. at p. 122).

¹ Because TigerTail™ includes FiberWire™, TigerTail™ infringes the ‘446 patent for the same reasons that FiberWire™ infringes.

² Because FiberStick™ includes a portion of FiberWire™, FiberStick™ infringes the ‘446 patent for the same reasons that FiberWire™ does.

**2. Arthrex's FiberWire™ and TigerWire™ Suture Products
Literally Infringe Claim 1**

33. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products³ literally infringe claim 1 of the '446 because they literally have all of the limitations of claim 1 as set forth below.

Claim 1 of the '446 Patent	FiberWire™ and TigerWire™ Suture Products
A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	The sterilized FiberWire™ and TigerWire™ suture is a braid of polyethylene (PE) and polyester (PET). ⁴ The PE and PET yarns are both continuous and discrete. The PE and PET are mechanically intertwined so that at least one PE yarn and one PET yarn are braided in direct intertwining contact. (DMI Ex. 318)
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The FiberWire™ and TigerWire™ suture is made from PE yarns that are made of a plurality of PE filaments. (Dreyfuss 9/16/05 Dep. at p. 50:21-51:1)

³ I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3). To the extent that I have not recited a specific Arthrex product by name or code, if any unrecited product includes any portion of a FiberWire™ or TigerWire™ suture, it would infringe claims 1, 2, 8, 9, and 12 of the '446 patent for the same reasons stated herein.

- ⁴ Q. And what incoming yarns are received by Pearsalls when Pearsalls manufactures and braids the bulk sutures made for Arthrex's FiberWire™ sutures?
- A. Incoming yarns would be ultra high molecular weight polyethylene and PET. (Dreyfuss 9/16/05 Dep. at p. 43:15-19)

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon, and aramid; and	The FiberWire™ and TigerWire™ suture is made from PET yarns that are made of a plurality of PET filaments. (Dreyfuss 9/16/05 Dep. at p. 64:14-17)
c) optionally a core.	Arthrex's FiberWire™ sutures have a core except for 4-0 FiberWire™. (DMI Ex. 318)

34. I understand that Arthrex has contended that it does not infringe claim 1 of the '446 Patent for several reasons. To the extent that I understand these positions, I will address them here. I reserve the right to amend or supplement my opinions based on Arthrex's full explanation of its positions.

35. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

36. As explained above, I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating

is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (DMI Ex. 78 at ARM1976).

37. The '446 Patent specifically contemplates, in the "Detailed Description of the Invention," that the braided sutures of the invention can be coated (Tab D at 6:5-21). The '446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (Tab D at 6:9-11). Thus, the '446 Patent's description of the invention as contemplating coatings supports my opinion that FiberWire™'s and TigerWire™'s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the '446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.⁵

38. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Tabs E (DMI Ex. 284), F (DMI Ex. 342), G (DMI Ex. 285).

⁵ My opinion is further supported because the '446 Patent claims a "suture." I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

39. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

40. It is my expert opinion and observation that the coating only appears on the surface of the braid.

41. I understand that Arthrex may argue that its FiberWire™ and TigerWire™ suture products do not literally infringe claim 1 because generally at least one end of its FiberWire™ and TigerWire™ suture products are “tipped.” I also understand that Arthrex may argue that FiberStick™ does not infringe because about 12 of the 50 inches of its FiberStick™ product is stiffened. With respect to FiberWire™ & TigerWire™, tipping means stiffening the end of the suture with Loc-Tite. (Dreyfuss 9/16/05 Dep at p. 122). To the extent I understand Arthrex’s position, I disagree with it.

42. In my opinion, the stiffening and tipping is irrelevant because the remainder of the FiberWire™, TigerWire™, and FiberStick™ suture products are not tipped or stiffened. Thus, at least a significant length of the FiberWire™, TigerWire™ and FiberStick™ suture products infringe. Therefore, regardless of the tipping and stiffening, FiberWire™, TigerWire™, and FiberStick™ infringe for the reasons set forth above.

43. Moreover, it is generally known that multifilament sutures have tipped ends so that they do not fray. Because the claims of the ‘446 patent are directed to a multifilament suture, it would not make sense for a multifilament suture claim to eliminate almost all multifilament sutures because of such a basic characteristic, *i.e.* tipped ends.

44. As explained above, Arthrex’s TigerWire™ is substantially identical to Arthrex’s FiberWire™ except that one carrier of PET yarn is replaced with a black nylon strand.

Otherwise, Arthrex's FiberWire™ braid is no different than Arthrex's TigerWire™ braid.⁶ I understand that Arthrex contends that its TigerWire™ suture products do not infringe because they have one black nylon strand. To the extent that I understand Arthrex's argument, I disagree.

45. It is my opinion that the nylon marking strand in Arthrex's TigerWire™ suture is non-bioabsorbable and therefore does not materially affect the basic and novel characteristics of the invention in the '446 Patent. For one thing, nylon is expressly mentioned in claim 1 as one of the fiber-forming materials from which the second set yarn can be made. Thus, the inventors contemplated it as being part of their invention, not as changing the basic and novel characteristics of their invention. Further, the inclusion of nylon yarn instead of one yarn of PET (I understand that nylon makes up only 3.4% of TigerWire™ suture, DMI Ex. 318) does not materially affect the basic and novel characteristics of the invention because the braid is still a heterogeneous braid of non-bioabsorbable yarns of the type claimed, at least one yarn of PE is in direct intertwining contact with a PET yarn, and the nylon does not materially affect the yarns from contributing to the properties of the overall braided suture.

46. My opinion is supported by Mr. Dreyfuss' testimony. Mr. Dreyfuss testified on behalf of Arthrex that that the nylon in Arthrex's TigerWire™ suture products is for visual identification and has "minute differences in its feel and strength characteristics" (Dreyfuss 9/16/05 Dep. at p. 75:7-14). Since visual identification is not a basic and novel characteristic, the inclusion of a nylon marker band has no material effect on the basic and novel characteristics of the invention.

⁶ Q. Sure. Sure. Is the braid in any Arthrex TigerWire™ different than the braid used in Arthrex's No. 2 FiberWire™?

A. The braid, no. (Dreyfuss 9/16/05 Dep. at p. 31, line 24 – p. 32, line 2)

**3. Arthrex's FiberWire™ and TigerWire™ Needle Products
Literally Infringe Claim 2**

47. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products⁷ literally have all of the limitations of claim 2.

Claim 2	Arthrex's FiberWire™ and TigerWire™ needle products
The surgical suture of claim 1 wherein the suture is attached to a needle.	Each FiberWire™ & TigerWire™ suture needle product has a FiberWire™ suture attached to a needle (DMI Ex. 3).

**4. Arthrex's FiberWire™ and TigerWire™ Suture Products
Literally Infringe Claim 8**

48. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products⁸ literally infringe claim 8 of the '446 for the following reasons:

Literal FiberWire™ Structure	Claim 8
The surgical suture of claim 1 wherein the second set of yarns is PET.	Each FiberWire™ and TigerWire™ suture product has PET as a second set of yarns.

⁷ Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

⁸ I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

(DMI Ex. 318).

**5. Arthrex's FiberWire™ and TigerWire™ Suture Products
Literally Infringe Claim 9**

49. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products⁹ literally infringe claim 9 of the '446. I have used the following definition of "volume fraction of the first set of yarns in the braided sheath and core" which means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture. For the following reasons, FiberWire™ and TigerWire™ literally infringe claim 9 of the '446 patent for the following reasons:

Claim 9	Arthrex's FiberWire™ and TigerWire™ Products
The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to 80 percent.	Every Arthrex's FiberWire™ and TigerWire™ construction has a ratio of the cross-sectional area of UHMWPE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent. (DMI Ex. 318).

⁹ Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-75SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR-1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

6. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 12

50. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products¹⁰ literally have all of the limitations of claim 12.

Claim 12	Arthrex's FiberWire™ and TigerWire™ Needle Products
The surgical suture of claim 8 wherein the suture is attached to a needle.	Arthrex's FiberWire™ and TigerWire™ needle products have either a FiberWire™ or TigerWire™ suture attached to a needle. (DMI Ex. 3).

C. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Under the Doctrines of Equivalents

51. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial.

52. I understand that Arthrex contends that there is no literal infringement because the claim limitation with respect to the "first-fiber-forming material" is not present because, although FiberWire™ has "PE" or polyethylene, it has one type of "PE," ultra high molecular weight polyethylene (UHMWPE). If it is determined that "PE" as claimed does not mean

¹⁰ Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

polyethylene (*i.e.*, including UHMWPE), then it is my opinion that there is infringement under the doctrine of equivalents because any differences are insubstantial.

53. I have used the “function/way/result” test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™.

54. In my opinion, the “function” of the first fiber-forming material is the same as the function of UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	Function of Limitation Under the Doctrine of Equivalents	Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

55. My opinion regarding the “function” of the first fiber-forming material is supported by the ‘446 Patent. The ‘446 Patent explains that the first fiber forming material is “dissimilar” to the second fiber and the braid of dissimilar yarns provides “outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns” (Tab D at 2:50-52; 3:43-48). Further, the ‘446 Patent explains that it is possible to “tailor the physical” properties by “varying the type and proportion of each of the dissimilar fiber forming materials used” (Tab D at 2:58-61). Further, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (Tab D at 8:19-21).

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the “way” of the first fiber-forming material is the same as the “way” of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	“Way” of Limitation Under the Doctrine of Equivalents	Way UHMWPE performs its Function in FiberWire™ and TigerWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The “way” is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the “way” of the “first fiber-forming” element is supported by the ‘446 Patent. The ‘446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact. For example, the ‘446 Patent states in the “Summary of the Invention” section that the “the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction” and that the at least one yarn from the first set is in “direct

intertwining contact” with a yarn from the second set (Tab D at 2:40-44; *see also* 3:21-28; 3:40-45). The ‘446 Patent further explains that the heterogeneous braid properties are due to the “mechanical interlocking or weaving of the individual yarns” (Tab D at 2:56-58; 3:43-48). Also, during the prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct “intertwining” contact of dissimilar yarns (December 2, 1992 Office Action at 2, emphasis original).

59. Further, the ‘446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Tab D at 4:9-59). The ‘446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (Tab D at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these “preferred embodiments,” and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

60. It is my opinion that the UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products have the same “way” as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex’s FiberWire™ and TigerWire™ products is

braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex's and Pearsalls' testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Dreyfuss 9/16/05 Dep. at p. 99-107).

61. In my opinion, the "result" of the first forming material is the same as the result of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	"Result" of Limitation Under the Doctrine of Equivalents	Result of UHMWPE in FiberWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

62. My opinion regarding the "result" of the first-forming material is supported by the '446 Patent. For example, the '446 Patent explains that the "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials" (Tab D at 2:49-52). Further, the '446 Patent states that the "types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties." (Tab D at 1:51-56).

63. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. (Arthrex supplemental response to Interrogatory No. 3) In FiberWire™, when

the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET.

64. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

Q What did you understand Mr. Grafton to mean when he said:

"Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".

What did you understand that to mean?

A Yes, that he wanted a braid which was more -- not so stiff.

Q As the 100% ultra high molecular weight polyethylene?

A Yes. (Hallet 1/12/06 Dep. at p. 306:20-307:4, DMI Ex. 324)

Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?

A Yes. (Hallet Dep. at p. 307:10-14, DMI Ex. 324)

65. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Tab D at 2:58-61).

66. In summary, if it is determined that PE is not PE (does not include UHMWPE), it is my opinion that the ultra high molecular weight polyethylene in Arthrex's FiberWire™ and TigerWire™ suture products is equivalent to the claimed PE because it performs the same function, in the same way to achieve the same result. Any differences are insubstantial in the context of the invention.

VI. Opinions Regarding Contributory Infringement

67. I understand that contributory infringement is defined in 35 U.S.C. §271(c), which provides:

Whoever offers to sell or sells within the United States or imports into the United States a component of a Patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a Patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

68. I understand that an act of actual direct infringement is necessary for a finding of contributory infringement. If there is direct infringement, then there is contributory infringement if the remaining requirements of the statute are satisfied.

69. I have been asked to provide my opinion as to whether Pearsalls has sold within the United States or imported into the United States a component of a patented suture that constitutes a material part of the invention in claims 1, 2, 8, 9 and 12 of the '446 patent. It is my opinion that Pearsalls has sold within the United States or imported into the United States a component of a patented suture constituting a material part of the invention in claims 1, 2, 8, 9 and 12 of the '446 patent.

70. It is my understanding that Pearsalls makes all of the braids used in Arthrex's FiberWire™ and TigerWire™ suture products. (Arthrex's Response to Mitek Interrogatory #2). Pearsalls imports into the United States unsterile, FiberWire™ and TigerWire™ suture that has not been cut to length or tipped. I personally observed the Pearsalls braided product at the final inspection stage before shipment. Pearsalls also sells within the United States this unsterile, FiberWire™ and TigerWire™ suture to R.K. Manufacturing (Ponton Dep. at p. 17:23-18:12).

71. It is my opinion that the unsterile FiberWire™ and TigerWire™ that Pearsalls imports and sells is a component of the invention of claims 1, 2, 8, 9 and 12 of the '446 Patent. The imported and sold FiberWire™ and TigerWire™ has the same construction as that sold by Arthrex except for some processing operations such as tipping, attachment to anchors or needles, and sterilization. (Ponton Dep. at p. 18:18-21). Thus, the imported and sold FiberWire™ and TigerWire™ has all of the limitations of claims 1, 2, 8, 9, and 12 except that it is not sterilized. It has a braid construction of polyethylene and PET in direct intertwining contact. Further, each has a core except for size 4-0 FiberWire™. Thus, the FiberWire™ and TigerWire™ that is sold and imported by Pearsalls is a component of the claims of 1, 2, 8, 9, and 12 and a material part of the invention of claims 1, 2, 8, 9, and 12.

72. I have been asked to provide my opinion as to whether the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use for infringement of claims 1, 2, 8, 9, and 12 of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use. It is my opinion that the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use in an infringement of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. The '446 Patent claims a suture. It is my understanding that RK Manufacturing does nothing to alter the FiberWire™ and TigerWire™ surgical braid. (Ponton Dep. at p. 18:18-21). The FiberWire™ and TigerWire™ imported and sold by Pearsalls has no known use other than as a suture, which is claimed in the '446 Patent. Thus, the FiberWire™ and TigerWire™ that is imported and sold by Arthrex is not a staple article of commerce and has no known substantial noninfringing use other than that that has been identified. (Pearsalls' Answers to Mitek's First Set of Interrogatories).

VII. Other Issues

73. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ that are marketed by Arthrex are due to the patented invention, a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the heterogeneous non-bioabsorbable braid.

74. For example, Arthrex markets that FiberWire™ has superior strength, increased stiffness, and has been “enthusiastically endorse[d]” for “its feel.” (DMI Ex. 7 at 2). FiberWire™’s and TigerWire™’s ultra high molecular weight polyethylene braided yarns contribute to FiberWire™ and TigerWire™’s strength and stiffness (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 267). Further, FiberWire™’s and TigerWire™’s PET contributes to the flexibility of the braid (DMI Ex. 324). Notably, the patented invention of claims 1, 2, 8, 9, and 12 includes a heterogeneous braid of PE and PET. Further, the ‘446 patent explains that a heterogeneous braid of dissimilar materials in direct intertwining contact can contribute to the overall properties of the heterogeneous braid (Tab D at 2:50-52; 3:43-48). Further, the ‘446 patent teaches that the braided yarns can be tailored in type and amounts to obtain the properties of each (Tab D at 2:58-61). FiberWire™ and TigerWire™ do just that by braiding polyethylene and PET. Thus, it is my opinion that benefits touted by Arthrex are due to the patented invention.

75. Arthrex’s and Pearsalls’ development of FiberWire™ and TigerWire™ confirms my opinion. For example, Mr. Hallet testified that in the development of FiberWire™ he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of

UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

76. It is my opinion that the braiding of dissimilar materials in direct intertwining contact in FiberWire™ contributes to the properties advertised by Arthrex in its marketing literature. For example, Arthrex has marketed that “that FiberWire™ is a “Braided Polyblend Suture” that it is “revolutionizing Orthopaedic Surgery” (DMI Ex. 7 at 1). I also note that Arthrex’s claims that its FiberWire™ heterogeneous braid has superior properties is supported by “multiple scientific publications” (DMI Ex. 7 at 2). Thus, Arthrex is highlighting the braiding of dissimilar materials as claimed in claims 1, 2, 8, 9, and 12 of the ‘446 Patent.

77. Further, Arthrex has made many assertions that FiberWire™’s heterogeneous braid is superior to Ethibond’s homogeneous braid. For example, Arthrex claims that the FiberWire™ is “twice as strong” as “polyester suture” (DMI Ex. 9 at 2; DMI Ex. 10 at 2; *see also* DMI Ex. 11; DMI Ex. 24 at ARM001473). Arthrex also asserts that “FiberWire™ has twice the strength of the similar *sized generic suture* with superior feel, tie ability, and lower knot profile” (DMI Ex. 13; *emphasis added*). Arthrex claims that its studies show that FiberWire™ has better knot strength than “Ethibond Excel braided polyester suture” (ARM002177-8; ARM002181-83; ARM002188-2191). It is my opinion that the braiding of polyethylene and PET in direct intertwining contact contributes to FiberWire™’s properties of strength and flexibility that Arthrex markets with respect to Ethibond.

78. At trial, I may use demonstrative exhibits. For example, I may use demonstrative exhibits to explain the design and construction of Arthrex’s FiberWire™ and TigerWire™ suture products, to explain infringement, and to explain the other opinions that I have set forth in my report.

Dated: March 3, 2006

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**David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers**

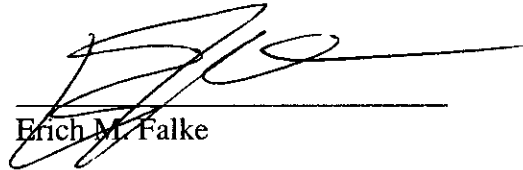
CERTIFICATE OF SERVICE

I certify that the foregoing Expert Report of Dr. David Brookstein was served by e-mail without exhibits and Federal Express overnight mail (Saturday delivery) with exhibits on March 3, 2006 on the following:

Charles W. Saber
Dickstein, Shapiro, Morin & Oshinsky, LLP
2101 L. Street, NW
Washington, DC 20037-1526.

Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109

Dated: March 3, 2006



Erich M. Falke

EXHIBIT 14

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Expert Report of Dr. David Brookstein

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

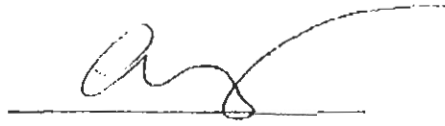
2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

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Dated: March 3, 2006

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David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

I have considered all or part of the following materials in rendering my opinions
expressed above.

United States Patent No. 5,314,446 and its prosecution history

DMI Ex. 3
DMI Ex. 4
DMI Ex. 5
DMI Ex. 7
DMI Ex. 8
DMI Ex. 9
DMI Ex. 10
DMI Ex. 11
DMI Ex. 12
DMI Ex. 13
DMI Ex. 14
DMI Ex. 17
DMI Ex. 20
DMI Ex. 24
DMI Ex. 30
DMI Ex. 31
DMI Ex. 32
DMI Ex. 33
DMI Ex. 56
DMI Ex. 60
DMI Ex. 61
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DMI Ex. 63
DMI Ex. 64
DMI Ex. 67
DMI Ex. 78
DMI Ex. 81
DMI Ex. 83
DMI Ex. 101
DMI Ex. 102
DMI Ex. 116
DMI Ex. 118
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DMI Ex. 123
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DMI Ex. 126
DMI Ex. 131

DMI Ex. 138
DMI Ex. 164
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DMI Ex. 310
DMI Ex. 311
DMI Ex. 312

DMI Ex. 313
DMI Ex. 318
DMI Ex. 324
DMI Ex. 325
DMI Ex. 342
ARM 2177-78
ARM 2181-83
ARM 2188-91
ARM 25451-52
ARM 25590
Kevin Grieff deposition transcript and exhibits
Brian Hallet deposition transcript and exhibits
Mark Steckel deposition transcript and exhibits
Peter Dreyfuss deposition 9/16/05 including exhibits

EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Rebuttal Expert Report of Dr. David Brookstein

I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

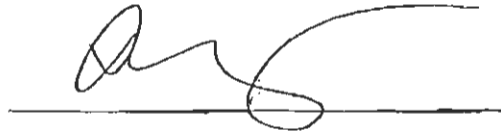
II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.

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EXHIBIT 484
04cv12457

68. I reserve the right to comment further on Dr. Mukherjee's analyses and report when more information about the analyses becomes available. I may use trial demonstratives to explain my opinions.

Dated: April 13, 2006

A handwritten signature in black ink, consisting of a stylized 'D' followed by a series of loops and a long horizontal stroke.

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

I have considered all or part of the following materials in rendering my opinions expressed above.

United States Patent No. 4,413,110
United States Patent No. 5,314,446 and its prosecution history
United States Patent No. 6,716,234
DMI Ex. 3
DMI Ex. 4
DMI Ex. 5
DMI Ex. 7
DMI Ex. 8
DMI Ex. 9
DMI Ex. 10
DMI Ex. 11
DMI Ex. 12
DMI Ex. 13
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ARM 2181-83
ARM 2188-91
ARM 25451-52
ARM 25590
ARM 7842-7940
Kevin Griefff deposition transcript and exhibits
Brian Hallet deposition transcripts and exhibits
Mark Steckel deposition transcript and exhibits
Peter Dreyfuss deposition transcripts and exhibits
Donald Grafton deposition transcript and exhibits
Ashley Holloway deposition transcript and exhibits
Ann Waterhouse deposition transcript and exhibits
Marks' Standard Handbook for Mechanical Engineers, page 6-155
Production and Applications of Polypropylene Textiles, pages 51-56
Generic Source-Based Nomenclature for Polymers (IUPAC Recommendations 2001)
Shakespeare Monofilaments website
 Specialty/High Performance Monofilaments – PVDF
 Polyolefin Monofilaments – PP
 Polyester Monofilaments – Standard Polyester
 Nylon Monofilaments – Nylon 6,6
Dyneke website
 Vilene – Monofilament P.V.D.F.
Mechanics of Elastic Performance of Textile Materials, pages 611-627
Summary of Pearsalls Batch Records
Arthrex's Responses to DePuy Mitek's Interrogatory No. 3
DePuy Mitek's Responses to Arthrex's Interrogatory No. 2
DePuy Mitek's Responses to Arthrex's Interrogatory No. 18
Pearsall's Responses to DePuy Mitek's Interrogatory No. 1

EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Supplemental Expert Report of Dr. David Brookstein

I. Background Information

1. Based on new information presented to me since my last report, I submit this supplemental report. Additional information that I have reviewed in forming my opinions is attached as Exhibit II.

II. Summary of Opinions

2. The samples tested by Dr. Gitis that he labeled "coated" and "uncoated" were manufactured differently. These manufacturing differences affect FiberWire's UHMWPE/PET braid. Therefore, it is my opinion that neither Dr. Gitis nor Dr. Mukherjee can make any scientifically reliable conclusions about the effect, if any, of FiberWire's coating based on Dr. Gitis' tests because they could not and did not determine what effects may be due to the coating and what effects may be due to the manufacturing differences between the samples (*e.g.*, the differences by which the UHMWPE/PET braids were made).

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EXHIBIT 485
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surgery (Ex. AAA, Burks Dep. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

Dated: July 14, 2006

A handwritten signature in black ink, consisting of a large, stylized 'D' followed by a series of loops and a long horizontal stroke extending to the right.

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

List of Additional Materials Considered

Deposition Transcript of Mr. Lewis with exhibits
Deposition Transcript of Mr. Hallet from June 30, 2006 with exhibits
Steven B. Warner, *Fiber Science* 1995
Deposition Transcript of Dr. Gitis with exhibits
Deposition Transcript of Dr. Mukherjee with exhibits
CETR Testing data
Pearsalls documents 008433-008473
CETR documents 0001-79
FiberWire Samples Ex. 388, 390, 438, 429, 389, 428, 235, 236, 237
Dr. Burks Transcript with exhibits
"An Experimental Method for Determining the heat Transfer Coefficient of Polymeric Fibers and Yarns During Rapid Convective heating" by R. Brooks published in The Journal of the Textile Institute 1984, No. 6, I then pp. 398-404.
DM. Ex 430
DM. Ex. 433
DM. Ex. 434
ARM25591
PR08325-08382

EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Amended Supplemental Expert Report of Dr. David Brookstein

I. Background Information

1. Based on new information presented to me since my last report, I submit this supplemental report. Additional information that I have reviewed in forming my opinions is attached as Exhibit II.

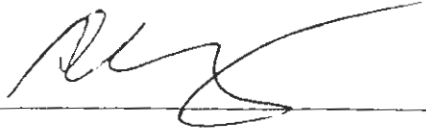
II. Summary of Opinions

2. The samples tested by Dr. Gitis that he labeled "coated" and "uncoated" were manufactured differently. These manufacturing differences affect FiberWire's UHMWPE/PET braid. Therefore, it is my opinion that neither Dr. Gitis nor Dr. Mukherjee can make any scientifically reliable conclusions about the effect, if any, of FiberWire's coating based on Dr. Gitis' tests because they could not and did not determine what effects may be due to the coating and what effects may be due to the manufacturing differences between the samples (e.g., the differences by which the UHMWPE/PET braids were made).

DEPUY MITEK
EXHIBIT 486
04cv12457

surgery (Ex. AAA, Burks Dep. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

Dated: July 24, 2006

A handwritten signature in black ink, appearing to read 'David Brookstein', is written over a horizontal line.

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

Amended List of Additional Materials Considered

Deposition Transcript of Mr. Lewis with exhibits
Deposition Transcript of Mr. Hallet from June 30, 2006 with exhibits
Steven B. Warner, *Fiber Science* 1995
Deposition Transcript of Dr. Gitis with exhibits
Deposition Transcript of Dr. Mukherjee with exhibits
CETR Testing data
Pearsalls documents 008433-008473
CETR documents 0001-79
FiberWire Samples Ex. 388, 390, 438, 429, 389, 428, 235, 236, 237
Dr. Burks Transcript with exhibits
"An Experimental Method for Determining the heat Transfer Coefficient of Polymeric Fibers and Yarns During Rapid Convective heating" by R. Brooks published in The Journal of the Textile Institute 1984, No. 6, I then pp. 398-404.
DM. Ex 430
DM. Ex. 433
DM. Ex. 434
ARM25591
PR08325-08382
TestWorks®4 "Continuing to set the standard for material, component, and subassembly testing software"
Gordon Laboratory Seminar Series Lent 2006
ASTM International, Designation: D 638-03, "Standard Test Method for Tensile Properties of Plastics"